EXHIBIT C

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
CAMDEN VICINAGE
MDL No. 2875
----------x
IN RE:

VALSARTAN, LOSARTAN and IRBESARTAN PRODUCTS
LIABILITY LITIGATION
----------x

August 13, 2021
9:12 a.m.

VIDEOTAPED DEPOSITION of STEPHEN LAGANA, MD, held at the offices of Greenberg Traurig LLP, located at 445 Hamilton Avenue, 9th Floor, White Plains, New York 10601, before Anthony Giarro, a Registered Professional Reporter, a Certified Realtime Reporter and a Notary Public of the State of New York.

APPEARANCES:

MAZIE SLATER KATZ & FREEMAN LLC
103 Eisenhower Parkway 2nd Floor
Roseland, New Jersey 07068
973.228.9898

BY: ADAM M. SLATER, ESQ.
CHRISTOPHER J. GEDDIS, ESQ.
aslater@mazieslater.com
cgeddis@mazieslater.com

Counsel for Plaintiffs

GREENBERG TRAURIG LLP
Terminus 200
3333 Piedmont Road, N.E., Suite 2500
Atlanta, Georgia 30305
678.553.2385

BY: VICTORIA DAVIS LOCKARD, ESQ.
(via Zoom)
LORI COHEN, ESQ.
BARDIA SANJABI, ESQ.
lockardv@gtlaw.com
cohenl@gtlaw.com
sanjabib@gtlaw.com

APPEARANCES (Cont.):

GREENBERG TRAURIG LLP
500 Campus Drive, Suite 400
Florham Park, New Jersey 07932
973.443.3571
BY: KENNETH DZIKOWSKI, ESQ.
dzikowskik@gtlaw.com

Counsel for Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Actavis Pharma, Inc., and Actavis LLC

PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI, LLP
38th Floor, One Oxford Centre
Pittsburgh, Pennsylvania 15219
412.263.1816
BY: CLEM C. TRISCHLER, ESQ.
cct@pietragallo.com

Counsel for Mylan Pharmaceuticals and Mylan Laboratories, Ltd.

APPEARANCES (Cont.)

BARNES & THORNBERG
2029 Century Park East, Suite 300
Los Angeles, California 90067-2904
310.284.3880
BY: KARA M. KAPKE, ESQ.
(via Zoom)
kara.kapke@btlaw.com

Counsel for CVS Pharmacy, Inc., and Rite Aid Corporation

CIPRIANI & WERNER, P.C.
450 Sentry Parkway
Blue Bell, Pennsylvania 19422
610.567.0700
BY: JILL FERTEL, ESQ.
(via Zoom)
jfertel@c-wlaw.com
Counsel for CVS Health Co., Aurobindo Pharma USA, Inc., Aurolife Pharma, LLC, Aurobindo Pharma, Ltd.

HILL WALLACK LLP
21 Roszel Road
Princeton, New Jersey 08540
609.924.0808

BY: NAKUL Y. SHAH, ESQ.
(via Zoom)
nshah@hillwallack.com

Counsel for Hetero Labs/Hetero Drugs

APPEARANCES (Cont.):

HUSCH BLACKWELL LLP
190 Carondelet Plaza, Suite 600
St. Louis, Missouri 63105
314.480.1500
BY: MATTHEW D. KNEPPER, ESQ.
(via Zoom)
matt.knepper@huschblackwell.com
Counsel for Cigna Corporation, Express Scripts Holding Company, Express Scripts, Inc.

DUANE MORRIS LLP
1875 NW Corporate Boulevard, Suite 300
Boca Raton, Florida 33431
561.962.2131
BY: PATRICK C. GALLAGHER, PH.D., ESQ.
(via Zoom)
pcgallagher@duanemorris.com

Counsel for Zhejiang Huahai Pharmaceutical Co., Ltd., Solco Healthcare LLC, Prinston Pharmaceutical Inc., and Huahai U.S. Inc.

FALKENBERG IVES LLP
230 W. Monroe, Suite 2220
Chicago, Illinois 60606
312.566.4801

BY: KIRSTEN B. IVES, ESQ.
(via Zoom)
kbi@falkenbergives.com

Counsel for Humana

A P P E A R A N C E S (Cont.):

HINSHAW & CULBERTSON LLP
53 State Street, 27th Floor
Boston, Massachusetts 02109
617.213.7000

BY: GEOFFREY M. COAN, ESQ.
(via Zoom)
gcoan@hinshawlaw.com

Counsel for HJ Harkins Co., Inc.

ALSO PRESENT:

COREY WAINAINA (via Zoom), Videographer
BRAD MATTA (via Zoom), Esq., Viatris

THE VIDEOGRAPHER: Good morning, everyone. We are going on the record at 9:12 a.m., Eastern Time on Friday, August 13th, 2021. Please note that the microphones are sensitive and may pick up whispering, private conversations and cellular interference.

This is Media Unit 1 of the video-recorded deposition of Dr. Stephen Lagana, in the matter of In Re: Valsartan, Losartan, et al. This was filed in the United States District Court for the District of New Jersey, Camden, Vicinage. The docket number is 2875. This deposition is being held via video conference.

My name is Corey Wainaina from the firm Veritext Legal Solutions. And I am the videographer. The court reporter is Anthony Giarro from the firm Veritext Legal Solutions.

I am not authorized to

administer an oath, I am not related to any party in this action, nor am I financially interested in the outcome.

Counsel and all present in the room and everyone attending remotely will now state their appearances and affiliations for the record. If there are any objections to proceeding, please state them at the time of your appearance, beginning with the noticing attorney.

MS. COHEN: Good morning. This is Lori Cohen on behalf of the Teva entities, as well as the defense executive committee, and I'll be taking and asking questions.

MR. TRISCHLER: Clem Trischler, representing the Mylan entities.

MR. SANJABI: Bardia Sanjabi representing Teva.

MS. COHEN: Chris Geddis for the plaintiffs. And that will be everybody in the room.

D R. S T E P H E N L A G A N A, after having first been duly sworn by a Notary Public of the State of New York, was examined and testified as follows:

EXAMINATION BY
MS. COHEN:

Q So I think we're through the logistics of all this and thank you for bearing with us, Doctor. But because of issues and all the people, we want to make sure we get started correctly and have a smooth day.

So you and I met off the record in the hallway. My name is Lori Cohen. I'm with Greenberg Traurig. And we're here in our White Plains office. And I represent the Teva entities but also the executive committee defense. I'll be starting the questioning, asking a majority of the questions today on behalf of everyone, who I am and my role here. Okay?

A Understood.

Q You've now sworn to tell the truth.

Page 10

Would you like to read and sign the deposition so I don't forget to ask that question?
MR. SLATER: We'll talk about that later.
Q I think you've been deposed at least a couple of times before; is that correct?
A I have.
Q And I know -- tell me how many times you've been deposed.
A Two that I recall.
Q One of them was in the Benicar litigation with Mr. Slater; is that right?
A Yes.
Q What was the other one?
A It was a medical malpractice.
Q Was that the same one you testified at trial, the Matthews versus Leslie case?
A No.
Q What was the other deposition you gave?

Page 11

A I don't remember the name of any of the litigants. But the general gist was whether a patient had been released from the hospital too prematurely or not. And I was hired by the defense in that case.
Q Roughly what time frame was that? I know it was earlier than four years ago. But any idea when that was?
A Probably around four years ago.
Q Were you on the side of the hospital or the doctor?
MR. SLATER: Object to form.
A Might have been both. I don't entirely recall. But one or the other or both.
Q So I know you've been deposed before. Obviously, if you need to take a break for any reason, let me know. I'm not going to go through a whole long introductory spiel like sometimes you'll get about what my questions are. If you need a break, let me know. If I ask a question that

Page 12

doesn't make sense, please let me know. If I talk too fast, which sometimes happens, let me know also; is that okay?
A Thank you.
Q And I think we'll have a good communication today. But again, if there's anything that you need or I don't make myself clear about, please ask me; okay?
A Thank you.
Q And if you answer my questions, I'll assume you understood them.
A Okay.
Q I know you brought with you a number of items today. Also, counsel who retained you sent us a bunch of things. And we'll get through some of those logistics as we go.
But I take it you have with you what you think you need to answer questions today?
MR. SLATER: Objection. You can answer.
Q I notice you have your

Page 13

report there in laminated fashion, and you have that by your side; right?
A I do.
Q So as a little bit of background, my understanding in terms of your prior legal experience is that you've testified two times at trial, once in 2019, and that was a recent one, Matthews versus Leslie case in the Bronx Supreme Court?
A Yeah.
Q And that was a medical malpractice case, testifying about your field of specialty, that is anatomic pathology; correct?
MR. SLATER: Objection. You can answer.
A Well, I am an anatomic pathologist. And I've testified as both a pathologist and as a medical provider.
Q You agree that your field of specialty is anatomic pathology; correct?
MR. SLATER: Objection. You can answer.
A Yes. I'm a medical doctor

Page 14

with postgraduate training in anatomic pathology.
Q What you hold yourself out as, as an anatomic pathologist, when we look at your Web site or when we read your depositions, that sort of thing; correct?
MR. SLATER: Objection to form.
A Again, as a physician, I have a medical degree. So I have knowledge of medicine beyond just anatomic pathology; in fact, an anatomic pathologist needs to have grounding in general. But I am a practicing anatomic pathologist.
Q And let's just agree that you're a medical doctor or you wouldn't have an M.D.; correct?
A That's correct.
Q But beyond that in terms of specialization, your specialty is anatomic pathology; correct?
A Correct.
Q You've testified in another

Page 15

trial, other than Mathews, another med mal one?
A Correct.
Q Was that the same one you gave the recent deposition about the patient being released prematurely?
A No.
Q What was the other medical mal one?
A Other medical mal one was -- nothing at all that relates to this. It's something -- I forget if it was a hernia repair that maybe didn't go as planned. There was a bowel injury, along those lines.
Q That was the Matthews versus Leslie case in 2019.
Is it possible that you covered the same areas?
A Yeah.
Q You've done 30 to 40 cases where you've reviewed cases as an expert witness?
A I believe that's approximately correct.

Page 16

Q In the Benicar litigation, Mr. Slater and his law firm hired you; correct?
A Correct.
Q And in this case, you gave an expert witness report under Rule 26 like you did here; correct?
A I don't know what Rule 26 is.
Q You gave an expert report?
A I did.
Q And you also gave a deposition; correct?
A I did.
Q And Mr. Slater was there defending you; right?
A No, not on trial.
Q That's what we say when an attorney defends a deposition. I don't mean a trial.
He was there defending your deposition as an expert witness?
MR. SLATER: Objection.
A He was there as plaintiff's attorney. And I was an expert.

Page 17

MS. COHEN: Let's go off the record.
THE VIDEOGRAPHER: We are now off the record. The time is 9:23 a.m.
(A short recess was taken.)
THE VIDEOGRAPHER: We are now back on the record. The time is 9:31 a.m. Eastern Time.
Q So, Doctor, I'm going to give this another shot. Hopefully, I'll try to keep my voice up. And this will work. When we broke, we were talking about your work in the Benicar litigation.
In Benicar, you gave an expert witness report in that case, much like you did here; correct?
A Yes.
Q And then you also gave a deposition, and at the deposition was Mr. Slater present there; correct?
A Correct.
Q You talked about your review of cases.

Page 18

Does that sort of summarize and recap your expert witness work that you've done?
A Yeah. I would say so.
Q In this case, we'll go ahead, and we'll obviously be going through your report and some of the information that you've read today.
Let's just start with stating your full name for the record.
A Sure. Stephen Lagana.
Q And where do you practice?
A I'm on the faculty at Columbia University Medical Center.
Q And you're part of the anatomic pathology division, if you will?
A Yes.
Q And is that part of pathology, one division of pathology?
A Correct.
MS. COHEN: In this case, let's go ahead and mark his report. We'll make that Exhibit 1.
(The above-referred-to document was marked as Exhibit 1 for

Page 19

identification, as of this date.)
Q And we'll have that put up. I think you have that already.
A I do.
Q Now, in your report -- I just want to start looking a little bit here -- on page 1, you understand this is what we call your official expert witness report in this case; correct?
MR. SLATER: Objection.
A I do.
Q And although you didn't take an oath like you did at the deposition, you signed it on page 33; correct?
A I did.
Q If you go to page 33, is that date of July 26th incorrect?
A I don't remember.
Q We'll get that straight. I believe that --
THE VIDEOGRAPHER: Counsel, sorry to interrupt. You want to have the document and the witness for the video record?
MS. COHEN: No. We did not

Page 20

ask to have that put up there, please.
THE VIDEOGRAPHER: Going forward, if you do screen share a document, would you like to see the witness only or the document and the witness?
MS. COHEN: Yes. Let me make that clear. When we mark exhibits, I'll announce what the exhibit is. But we don't need to screen share it. People can pull it up if they want to. But I'm not asking for the document to be pulled up; okay?
THE VIDEOGRAPHER: Thank you.
Q Just on the date issue, Doctor, we have July 6th as the day that the report was sent to us by Mr. Slater.
I take it July 26th is just the wrong date?
A That sounds reasonable.
MS. COHEN: We'll mark the July 6th letter as Exhibit 2.

Page 21

(The above-referred-to document was marked as Exhibit 2 for identification, as of this date.)
Q And I'll show it to you. I take it, it was just a mistype, if you will.
A It might be.
Q I'll show you the letter, Exhibit 2, a July 6th letter where Mr. Slater sent the reports. Tell me if you've seen this before.
A I haven't seen that. Okay. I don't have an argument. It's certainly possible I mistyped the date. There's only one report.
Q Only one report.
You understand -- and, again, in this report, you start with a sentence that says, "This report sets forth my opinions with regard to the question of whether ingestion of NDMA and NDEA as a contaminant or impurity of Valsartan (hereinafter 'contaminated Valsartan') can cause cancer in humans."
You understood that was the

Page 22

question you were being called on to answer in this phase of the litigation; correct?
MR. SLATER: Objection. You can answer.
A I knew that that was the purpose of the litigation.
Q That was the question that Mr. Slater gave to you when he framed your question to you; correct?
MR. SLATER: Objection. You can answer.
A That's perhaps a little bit more narrow than everything I've looked at.
Q Right.
But you start your report by saying the question of whether -- and I won't repeat it again. That was the question that Mr. Slater told you, was the question for you to start with; correct?
MR. SLATER: Objection. You can answer.
A That was certainly the main

Page 23

issue. I don't know if that encompasses every aspect.
Q And that question was presented to you by Mr. Slater; correct?
A Yes.
THE VIDEOGRAPHER: We are now off the record. The time is 9:38 a.m. Eastern Time.
(A short recess was taken.)
THE VIDEOGRAPHER: We are back on the record. The time is 9:43 a.m. Eastern Time.
Q It sounds like in terms of the other plaintiffs' expert witnesses, you did not read their reports; correct?
A I did not.
Q You're aware the existence of some of the other plaintiffs' experts; correct?
A Correct.
Q You don't know anything about Dr. Panigrahi, who's also a pathologist; correct?
A No.
Q Never heard of him; correct?

Page 24

A No.
Q You don't know anything about his credentials; correct?
A Correct.
Q I turned to the defense experts, and I said there were nine defense experts, and I think you confirmed that you received Dr. Catenacci's, the oncologist, report?
A Correct.
Q And you said that you read the last part of that report?
A Correct.
MR. SLATER: Objection. Those are of a much broader conversation.
Q When did you receive that report?
A About roughly five days ago.
Q And in terms of volume you received, just that one, you don't know?
A That's right.
Q Did you ask for specific ones or were you just given that one?
A I didn't ask for specific

Page 25

ones. I think I asked Adam if there are any that were relevant that were talking about the same papers, given that I had very limited time. There wasn't much time between then and now. If there were any he thought I should read, I would be happy to do so.
Q He sent you back the Catenacci, the oncology defense expert report?
A Correct.
Q Are you aware of who the other eight are?
A I am not.
Q Were any of them mentioned to you?
A No.
Q Do you know who, for example, Dr. Chodosh is, a cancer biologist?
A No.
Q What about Dr. Gibb, an epidemiologist?
A No.
Q Do you know Dr. Johnson, a

Page 26

toxicologist who came out with a recent article on NDMA and NDEA?
A No.
Q Never heard of him?
A Not that I recall.
Q Did you read his article?
A We'd have to check the list.
Q Sitting here right now, do you have any recollection of reading Dr. Johnson's recent article that came out in 2021?
A I might recall the article. I don't recall the name. I'd have to see what article we're talking about.
Q And, again, to date, sitting here, you don't have any other expert reports on the defense, other than Dr. Catenacci, to your knowledge?
A Correct.
Q In terms of the materials in this case, and we'll get into some more of this as we go -- you provided to us -- let me start with this, your expert witness report, which we have marked as Exhibit 1 already. It has attached to it

Page 27

a list of the references cited. And it goes from pages 34 to 37.
Is it fair to say that at the time you issued your report, which is Exhibit 1, these were the materials you considered?
A Yes.
Q And either things that are referenced in the expert report or on that list; correct?
MR. SLATER: Objection.
A Everything on this list is referenced in the report.
Q Got it.
And we received over the last couple of days some supplemental lists which we'll mark at some point today. And some of that I think is contained in here.
But is it fair to say that everything -- again, in terms of issuing your opinions on July 6th, which is the date I think we agree it came out -- that all encompasses Exhibit 1?
MR. SLATER: Objection. You

Page 28

can answer.
A Well, it's a little bit of a hard question to answer because as far as specific issues related to causation, then these are the materials I relied on. But, of course, I didn't address this question in a vacuum. I addressed it as a doctor who's been to medical school and has practiced for however many years, ten years or so that I've been practicing.
So my thinking is shaped by not just the specific articles cited here, but my training and background and experience. But as far as specific reliances for this report, yes, they're all included here with the exception of the one that Chris should have provided to you last night. There was one article I got my citation mixed up. And I thought I was referencing two articles by the same person, published in the same year. So one reference is missing.
Q Understood. And I think you have that here. But let me ask it this way.

Page 29

I understand that your background, training and experience and all of that informs your opinions; correct?
A Correct.
Q That's the point you're making; right?
MR. SLATER: Objection. You can answer the question.
A Yes.
Q But in terms of specific references and materials reviewed, that's what's attached in the references that I just referred to, to your report; correct?
MR. SLATER: Objection. You can answer again.
Mischaracterization of testimony.
Q References cited, pages 34 to 37, those are the references you gave in your report; correct?
MR. SLATER: Objection. That's a continuation of a prior inappropriate question. I object. You can answer.

Page 30

A Yes, with the addition of the paper that we sent over last night.
Q The one article that Chris cited?
A Yes.
Q Let me give you the exact names so I have it here. Let's see. Mr. Geddis said first citation, 36, on page 16 should be Jakszyn P Gonzalez, CA, the nitrosamines article.
A Correct.
Q That's the document I'm talking about.
A Yes.
Q With that substitution, this reference list is what you had at the time to formulate your opinions; correct?
A Yes.
MS. COHEN: I want to mark his curriculum vitae. It's unfortunately not marked.
(The above-referred-to document was marked as Exhibit 3 for identification, as of this date.)
Q Let me hand that to you.

Page 31

A Okay.
Q Just confirm if that's your curriculum vitae.
MR. SLATER: This is now Exhibit 2?
MS. COHEN: Exhibit 3.
A It appears to be current up until the 5th of April.
Q And I have a quick question about this. I know your curriculum vitae from the Benicar litigation obviously was different. It's an earlier time, back in 2016.
Do you have a different curriculum vitae for different purposes or is this your current curriculum vitae for all purposes?
A This is my curriculum vitae for all purposes.
Q And so the one that was used in Benicar is just an updated, is what you're saying?
A I don't know what the CV for Benicar was. But Columbia University has a very precise format for promotion. And

Page 32

when I was preparing for a promotion a couple of years ago, two and a half years ago, I had to make a CV that conformed exactly to the Columbia format. And since then, I've only used this document which conforms with the Columbia format.
Q What promotion are you talking about? Are you talking about from assistant professor of pathology to associate professor of pathology?
A Precisely.
MS. COHEN: I'm going to have the Benicar marked as well and the attached curriculum vitae while we talk about this. And that one is attached there. So we'll mark it as Exhibit 4.
A Okay.
(The above-referred-to document was marked as Exhibit 4 for identification, as of this date.)
Q And what you're saying is, it was in a different format when you were an assistant professor?
MR. SLATER: Objection.

Page 33

You're saying what he just said.
Q It was a different format of your curriculum vitae?
MR. SLATER: I don't understand what the question is. Can you literally just walk me through the CVs?
MS. COHEN: Adam --
MR. SLATER: It's a confusing question.
MS. COHEN: Adam, you don't have to talk. No speaking objections. It's a very simple question.
Q Again, you had a very different curriculum vitae style and approach back in the Benicar litigation.
And I think you attribute that to going from assistant to associate; is that correct?
MR. SLATER: Objection to the form of the question. You can answer.
A Well, before I went for a promotion, I had a CV format that I

Page 34

probably got from a Microsoft Word template. And then when I decided to go for a promotion or was invited to go for a promotion, I had to put all the data in the Columbia format which is what you have before you.

Q And that was because you went from assistant to associate?

A Yes.

Q And that was in December of 2018; is that correct?

A Sounds correct.

Q That's because you went from assistant to associate professor. And was that in 2018?

A Yes.

Q Is there anything else in terms of the content of the CVs that you think would have been different?

MR. SLATER: Are you asking him to state and compare them one by one right now? Is that the question?

MS. COHEN: If you have an objection, say objection. I'm asking my questions.

Page 35

MR. SLATER: I'm asking you to clarify. Do you want to clarify? I object to the question.

Q Is there anything else that you know that's different between them?

A Well, there are specific things that Columbia requires in the Columbia format. And there may be -- no place for other things. And I might have included it in a more informal CV. So I can't be sure that everything substantive -- I mean everything important, should be the same. I don't know if there are minor things that either didn't get transferred or what have you.

Q Fair enough.

And other than, again, going from assistant professor of pathology with a specialty in anatomic pathology, from assistant to associate in 2018, what you do every day has been the same; correct?

MR. SLATER: Objection.

THE COURT REPORTER: It's hard to hear.

MR. SLATER: I objected to the form of the question.

THE COURT REPORTER: I'm very uncomfortable continuing under these circumstances. I'm sorry.

MS. COHEN: Maybe we'll just bring him in here or bring him in the hallway or something like that. Let's take a break. We'll take a break and do that.

THE VIDEOGRAPHER: We are now off the record. The time is 9:57 a.m. Eastern Time.

(A short recess was taken.)

THE VIDEOGRAPHER: We are back on the record. The time is 10:08 a.m. Eastern Time.

Q So, Doctor, thank you for being patient on all this.

A Sure.

Q And I just organized in front of you so we have it all. We have -- 1 is the report; 3 is the CV that went with your report; 4 is the Benicar

Page 37

report. We're waiting on a copy of 2 which is the letter. And then I'm going to mark as Exhibit 5, what was sent to us last night by Mr. Geddis.

Just again for completeness sake, is that the article you said you needed to be -- I think you had the wrong cite; is that right?

A Yeah. Incorrect citation.

Q So this article now is the right one that goes with your reliance list, if you will, reference list?

A Yeah. The reference that's in the -- that's in the report now is also the reliance and reference. This one was missing. So this adds to what's here.

Q I see what you're saying.

A It only replaces in that one specific sentence.

Q And two, I'm going to hand you this letter. That is the correct one --

MR. SLATER: I think we're all going to have to put our masks on

Page 38

if we're not questioning. I hate to do this. It's just too many people in here.
Q Again, this is Exhibit 2 which is the July 6th letter. And I do want to look at the last page of this. And --
MR. SLATER: Which exhibit is this?
MS. COHEN: Exhibit 2.
MR. SLATER: I don't think I have it. I have no e-mail on my computer.
Q So you have that in front of you. It says that your rate is $600 per hour, except for depositions and courtroom testimony, which is $5,000 per hour; is that correct?
A That's what it says. That is not correct.
Q That's not correct?
A No. That would be lovely. But, no, $6,000 per day for deposition and courtroom testimony.
Q Do you know why it says

Page 39

$5,000 an hour?
A I could only presume it's a typographical error.
Q But it's $6,000 per day?
A Yes.
Q Not $5,000 per hour?
A Correct.
Q We'll put that aside for now. Now, one thing I want to ask you is that -- well, let me ask.
In Dr. Chodosh's expert report, I know you haven't seen this, he says that the central question at this stage of this litigation is whether exposure to NDMA and/or NDEA at the doses to which plaintiffs were potentially exposed via ingestion of Valsartan and within the time frame of which they were potentially exposed could have caused the types of cancer in human beings that are claimed in this litigation.
You don't disagree that that's a central question, do you?
MR. SLATER: Objection for multiple reasons. You can answer.

Page 40

A Could you read it again, please?
Q Sure.
The central question of this stage of the litigation is whether exposure to NDMA and/or NDEA at the dosage to which plaintiffs were potentially exposed via ingestion of Valsartan and within the time frame of which they were potentially exposed could have caused the types of cancer in human beings that are claimed in this litigation; in other words, and I'll ask, adding in the doses and the time frames, you agree those are significant features of the question; right?
MR. SLATER: Objection. You could answer.
A I don't agree with everything in that statement.
Q Do you disagree that the doses matter?
MR. SLATER: Objection to this entire line because it's built on a false premise. You can answer.

Page 41

A Understanding that there is no safe dosage and that any exposure is likely to increase risk of cancer, I would -- from that baseline, I would agree that bigger doses for longer duration are worse than smaller doses for shorter durations. Likely, likely.
Q You wouldn't have any quarrel with an expert, whether on the defense side or the plaintiffs' side, that includes the issue of doses and the issue of time frame in terms of looking at this issue; correct?
MR. SLATER: Objection. You could answer.
A It's an extremely broad proposition. But in general, I think looking at the dose and length of exposure are both reasonable things to consider.
Q And should be considered when looking at the issue of general causation and cancer; correct?
MR. SLATER: Objection. You could answer.

Page 42

A Certainly, but with some humility for what we don't know, insofar as there is no safe baseline level of NDMA.
Q Your answer is those have to be considered; true?
MR. SLATER: Objection. You could answer.
A Those are factors amongst many which have to be considered.
Q Now, just to make sure I cover this, all of the information that you've obtained in this litigation that we have on the table list and that's referenced, did all of that come through Mr. Slater and his firm?
MR. SLATER: Objection. You can answer.
Q Putting aside your training and experience, all of the references and information came to you from Mr. Slater and his law firm; correct?
A Absolutely not.
Q You pulled some of it yourself?

Page 43

A Almost everything.
Q All the literature, you're talking about in your reference list?
MR. SLATER: Objection. You could answer.
A I didn't keep a record of what was -- what I found myself and what was provided by Mr. Slater. But roughly speaking, I would say 90-some-odd percent of the studies, I found myself, and maybe a few were sent by Mr. Slater. And, of course, all the corporate documents and deposition and stuff was provided by Mr. Slater.
Q All the depositions and corporate documents all came through Mr. Slater and his law firm, is what you're saying?
A Yeah.
Q You would agree that you have looked high and low and gathered the information, and there is not a single article, Peer Reviewed article that proves that NDMA and NDEA are known carcinogens in humans; correct?

Page 44

MR. SLATER: Objection. You could answer.
A Can you repeat the question?
Q Sure.
I said you've looked high and low, you've looked everywhere, you've gathered your references, and there's not a single article that establishes that NDMA and NDEA are known carcinogens in humans; correct?
MR. SLATER: Objection. You can answer.
A I totally disagree with that.
Q You have articles that prove in laboratory animals; correct?
MR. SLATER: Objection. You can answer.
A I wasn't done answering the question.
Q Okay.
A There are, as referenced in my report, a number of Peer Reviewed and scientific articles looking at dietary NDMA exposure in humans, some of which

Page 45

include tens of thousands of patients that do, in fact, show an association between dietary NDMA exposure in cancer. So that's one line of that.
As far as a single article, there's nothing in the medical literature that has definitively established by a single article, by the weight of evidence, the totality of the evidence. So looking at those dietary NDMA articles, my opinion to a reasonable degree of medical certainty is that NDMA ingestion is clearly associated with human carcinogenesis.
Q So you rely on the dietary articles in your report for an association; correct?
A Amongst others.
Q You cannot point us to any single Peer Review article that establishes causation in terms of human carcinogens with NDMA and NDEA; correct?
MR. SLATER: Objection. You can answer.
A It's a large question. It's

Page 46

hard to drill down to one -- to one, you know, short answer. To some extent, I could say that my -- my report deals entirely with that question and concludes that does, in fact, cause human cancer.

However, to try to answer the question, other than just saying read my report, we know the mechanisms by which NDMA causes cancer. It's stated by WHO and IARC that metabolism in experimental models, meaning animals and humans, is likely to be the same. And IARC concludes that NDMA is a probable human carcinogen.

And I agree with IARC's assessment based on both epidemiologic studies as they relate to diet, early indications about contaminated Valsartan itself and knowing the mechanism by which NDMA is a potent mutagenic compound.

Q Do you know the difference between association and causation?

A I do.

Q And are you familiar with that from -- let me strike that.

Page 47

I want to go back to my question which is, you could not point us to any single Peer Review article that establishes causation in terms of human carcinogens with NDMA and NDEA. And you point to, again, the dietary studies, your report, which we'll go through in great depth.

Can you point to any single Peer Review article that causes causation?

MR. SLATER: Objection. You could answer the question.

A As far as a single article, I think it's an unrealistic -- it's not the way that medical research is evaluated. You don't just look for one article that definitively proves causation. The way to do that would be to do a double blind randomized placebo controlled trial, wherein one group of people who is exactly the same as another group of people get fed massive doses of NDMA. And then you see how many cancers they get. And such a thing would be

Page 48

wildly unethical.

So we have to infer causation by applying the criteria -- I chose to use Bradford Hill's criteria, although there are other ways of distinguishing between association and causation. I chose Bradford hill. I looked at the totality of the evidence. And my opinion has landed in the same place with WHO and IARC and FDA.

Q We're going to go through all of the articles and your report. I'm just asking you, can you cite -- I'm not saying you can only look at one article.

Can you cite to us any article that establishes a Peer Review process, causation as a human carcinogen for NDMA and NDEA?

MR. SLATER: Objection. You can answer.

Q You would have it in your report if you could find it; right?

MR. SLATER: Objection. You can answer.

Q True?

Page 49

MR. SLATER: Objection. You can answer.

A I'm sorry. I think that's three things. I'm asking still about the first. What is the question?

Q Can you cite to us any article, Peer Review literature that establishes NDMA, NDEA as a human carcinogen?

MR. SLATER: Objection. You can answer.

A Well, consensus statements by IARC, WHO, FDA, EMA.

Q So the answer's no, no article that you can cite to?

MR. SLATER: Objection.

A I think I just said, or publications.

Q I'm asking about Peer Review literature.

A Those are Peer Review. Well, IARC, WHO are Peer Review.

Q We'll circle back to that.

You're here as a scientist; correct?

Page 50

MR. SLATER: Objection. You can answer.
A I'm here as a physician, medical scientist, yes.
Q You're not here as an advocate; correct?
A No.
Q And you're not leaning towards one side or the other as you look at this case?
A Well, I've drawn conclusions. I mean I have an opinion.
Q Before you got started, had you ever looked at the issue of NDMA and NDEA as a contaminant or impurity of Valsartan and carcinogen? Have you ever looked at that issue in any capacity outside of this case?
A I think, yeah. I must have seen it. It was in the news. I'm sure I looked at it to some extent.
Q You first got involved in this case by the invoices, I think in late 2020; correct?
A If that's what the invoices

Page 51

say, that sounds correct.
Q You started off with an hour-long meeting with Mr. Slater; correct?
A Sounds correct.
Q He gave you the question that is from the plaintiffs' perspective, whether ingestion of NDMA and NDEA as a contaminant or impurity of Valsartan can cause cancer in humans; correct?
A I don't remember the details of what we spoke about. I mean I'm sure we spoke about the case in general.
Q He gave you your assignment; correct?
MR. SLATER: Objection.
A He asked me to look at the issue.
Q At that issue; right? That question; correct?
MR. SLATER: Objection. You can answer.
A He asked me to look at the issue of whether NDMA ingestion can cause cancer in humans.

Page 52

Q You had never studied that in any capacity prior to your meeting with Mr. Slater; correct?
A Whether NDMA causes cancer?
Q Yes.
A I probably had looked at it before.
Q Can you tell me where?
MR. SLATER: I'm going to direct you only to answer to the extent that you are not bound by any confidentiality outside of this case.
Q Let me ask it this way. I'm not asking about anything that's confidential.
In your role as a clinician, an M.D., did you ever look at this issue before you sat down with Mr. Slater?
MR. SLATER: Objection to the term "this issue." You can answer.
MS. COHEN: This issue of NDMA and NDEA and relationship with cancer.
Q Did you ever in any capacity

Page 53

in your real world life outside of expert witness work look at this issue?
A You know, there have been times when this has come up in the late press. And so I have, you know, looked to some extent at this issue. But as part of my practice of medicine, no.
Q As a scientist or clinician or M.D., you had never looked at this issue; correct?
MR. SLATER: Objection. You can answer.
A Not that I recall.
Q And so all of your knowledge, education, experience is derived in litigation in terms of the seminal question at issue in this case; true?
MR. SLATER: Objection. You can answer.
A To a large extent, this question is about carcinogenesis and carcinogenicity. And I am an anatomic pathologist with a lot of experience diagnosing cancers, staging cancer. So I

Page 54

am an expert on cancer.
So that, I think, is probably why Mr. Slater contacted me. But as for the sort of ways in which cancer's developed, I know very well, I understand very well the role of NDMA. Precisely in cancer causation, I learned largely by doing research for this litigation.
Q. We'll unpack that statement. I'm going to ask a straightforward question, though.
In terms of this question, whether ingestion of NDMA and NDEA as a contaminant or impurity of Valsartan can cause cancer in humans, that question, all of your knowledge, research came in litigation; correct?
MR. SLATER: Objection. You can answer.
A. Well, before this started, I certainly knew that NDMA was a potent laboratory carcinogen for animals. As far as how carcinogenic it was or was not for humans, I don't recall having looked

Page 55

at that literature in detail before the litigation.
Q. And it's not an issue that's come up in your clinical practice; true?
A. True.
Q. And, in fact, let's go into -- we've talked a little bit about your expert witness work, your legal work. Let me ask you one more question before I move on.
Have you ever consulted with -- on the issue of NDMA and NDEA with anyone other than Mr. Slater?
MR. SLATER: You can answer the question with a yes or no. But if you consulted in the capacity that was not disclosed with anybody else, then you won't be allowed to give any of those details. But you can say yes or no to that first question.
THE WITNESS: Okay.
A. Yes.
Q. Other plaintiffs' attorneys?
MR. SLATER: Don't answer the question. I'm happy to talk

Page 56

about this. But there's probably people that would assert objections to him answering those questions. And I'm not involved with that.
MS. COHEN: Let's talk on a break.
MR. SLATER: So I'm not -- I don't think he should answer that question.
Q. Well, let me ask the question.
Have you consulted with the defense at any point in time on NDMA and NDEA?
MR. SLATER: Isn't that the flip side to the same question?
MS. COHEN: I'm phrasing the question. If he doesn't answer, we'll have it on the record.
MR. SLATER: Why don't you come back to this. And I'll talk to you. I'm telling you it's a question that he can't answer. It's the flip side of the other question. I'm happy to talk to you about it during

Page 57

a break.
MS. COHEN: Okay.
Q. And you made a comment a minute ago about this is why Mr. Slater -- why you thought Mr. Slater called you.
The reason he called you is because you and he had worked together before; correct?
MR. SLATER: Objection. You can answer.
A. I would expect and hope that the reason he called me is because he knows that I am an expert on cancer development and that I would give a thorough and fair evaluation of the literature.
Q. We know you worked for Mr. Slater and his firm on Benicar, that you did a report in 2016, and that you did a deposition in 2017; correct?
A. Yes.
Q. And you and he had worked on some cases before that too; is that right?

Page 58

A No.
Q Had you worked on another case with him at any point in time?
A Not that I recall.
Q Just Benicar, is what you're saying?
A Yes.
Q I think in the deposition, there was reference to another case. But I think that was part of Benicar cases, perhaps.
MR. SLATER: Objection. Do you want to tell us what you're specifically referring to?
Q Did you do work with Mr. Slater on anything that was not Benicar-related at any point in time?
A No. We worked on -- there were several Benicar cases.
Q And you're saying other than -- after Benicar, this is the next involvement you had with Mr. Slater and his law firm?
A Yes.
Q This being Valsartan?

Page 59

A Correct.
Q And the question of NDMA and NDEA; correct?
A Yes.
Q When we look at your Web site, the Columbia Web site, you're listed as -- I want to move to your medical-clinical practice as opposed to your legal work for just a moment.
(The above-referred-to document was marked as Exhibit 5 for identification, as of this date.)
Q I'll give you Exhibit 5.
Do you recognize this as part of your Columbia Web site?
A Yes. Looks correct.
Q And what is listed as your specialties: Pathology-anatomic, gastrointestinal pathology; correct?
A Yes.
Q And that's consistent with how you hold yourself out in terms of your specialty; correct?
MR. SLATER: Objection. You can answer.

Page 60

A I'm a surgical pathologist or an anatomic pathologist.
Q Well, there's a difference between them, aren't there?
A Between anatomic pathology and surgical pathology?
Q Yes.
A Surgical pathology is a subcategory of anatomic pathology.
Q Let's move a couple of pages in -- one, two, three pages in on that, Exhibit 5. This also says -- again, more description about what you do and who you are -- "I am a surgical pathologist with sub-specialty expertise in GI and liver pathology"; correct?
A Correct.
Q And that's accurate; right?
A It is.
Q And what that means is that you primarily study tissues --correct?-- and samples and specimens removed from patients; correct?
MR. SLATER: Objection. You can answer.

Page 61

A Yeah. We look at everything from -- well, we look at everything from clinical history of a patient to the gross organ that's removed. That has to be removed from the patient in surgery. We look for important parts -- if it's a cancer case, we look at a tumor, we make slices of that, turn that into slides, which we stain, and look at glass slides under a microscope, make diagnoses, stage cancers.
Q But in terms of how you spend your time as a clinician, first of all, I guess, you said in your report or your deposition that 75 percent of your time is on clinical commitment and reviews of specimen; correct?
A Yes.
Q And that means again as an anatomic or surgical pathologist; correct?
A Correct.
Q You're not a cytopathologist; correct?
A Correct.

Page 62

Q You're not a forensic pathologist; correct?
A I do perform autopsies, but medical autopsies which are different than forensic autopsies.
Q I think I read in your 2019 deposition that you hadn't done any full autopsies for two years at that point which would have been 2017.
Has that changed at all?
A Yes. I did autopsies during COVID.
Q And is that because of need?
A Yes.
Q But you don't hold yourself out as a forensic pathologist; correct?
MR. SLATER: Objection. You can answer.
A Not a forensic pathologist in the sense of going to crime scenes and investigating, no. Medical autopsies, I am fully capable of performing.
Q For a while, you hadn't been doing them?
A Right.

Page 63

Q How many years was that?
A I did them for a few years. I stopped doing them for a few years. I went back to them last year. I stopped again now. So I didn't keep careful track of it.
Q And you're not a molecular pathologist; you don't specialize in DNA and RNA sequencing; correct?
MR. SLATER: Objection. You can answer.
A Molecular pathology has become really a very integral part of being an anatomic and surgical pathologist. So I do have a very good working knowledge of molecular pathology. And I'm not versed in it in any way. Mainly, though, in interpreting results, I could not run the machine per se to do it.
Q You don't hold yourself out -- that's not one of the things you put on your CV or on your Web site that you're a molecular pathologist; correct?
MR. SLATER: Objection. You

Page 64

can answer.
A I'm a codirector of a committee that actually comes up with molecular testing protocols. So I interface between the surgical pathology division and the molecular pathology division to come up with optimal testing protocols.
So if someone has a colon cancer diagnosed at Columbia, they get a number of ancillary tests, both within the molecular lab and with anatomic pathology. And I'm the codirector of the committee that decides what those best tests are.
Q If we look at your curriculum vitae, either Version 1 from Benicar, Version 2 from Valsartan, we don't see anything calling yourself a molecular pathologist; correct?
A I mean the administrative role I just described is on it. But, no, a molecular pathologist is someone who can run the machines. I can't run the machines. But I am going to say -- and

Page 65

I'll defend this -- that I can certainly interpret molecular results very well.
Q I went through all the Web sites that I could find online that describe you. And they all list you as an anatomic pathologist.
You don't disagree with that, do you?
MR. SLATER: Objection. You can answer.
A No. I'm an anatomic pathologist.
Q That's how you hold yourself out to the world; correct?
A Yes.
Q Anatomic pathology again primarily consists of tissue evaluation from individual cells, finding the lacerations, evaluations of specimens and tissues; correct?
MR. SLATER: Objection. You could answer again. We just went through this for ten minutes.
A So anatomic pathology is the study of disease in organs and cells.

Page 66

And so that is what I do. I look at gross organs. I may look at a whole body in the case of an autopsy. I may look at cells. I may do ancillary tests to look at subcellular structures. Any of that would be part and parcel of my daily practice.

Q And, again, 75 percent of your time is on this anatomic pathology clinical commitment and review of specimen, I think is how it was described. Does that sound right?

MR. SLATER: Objection. You can answer.

A Yeah. Actually, a lot of that also entails teaching. If I have a resident or a fellow assigned to me while I'm doing that work, I'm also teaching.

Q I'll tell you in a recent trial transcript, Mathews versus Puente case in the Bronx, that was in 2019, nothing has changed about your practice since 2019; correct?

MR. SLATER: Objection. You could answer.

Page 67

A It's generally the same, yeah.

Q And what you said there -- and I could show you if you want me to get out the transcript --

MR. SLATER: Let's do that.

MS. COHEN: That's fine. We'll give you a copy of this. We'll mark that as Exhibit 6.

(The above-referred-to document was marked as Exhibit 6 for identification, as of this date.)

MR. SLATER: What page of Exhibit 6?

Q Do you recall giving this testimony in the Bronx court?

A I do.

Q And you recall turning to the jury giving this testimony about what you did, what you do?

A What page are we looking at?

Q Page 5.

This is where you're in the medical malpractice case as an expert for the defense, I believe; correct?

Page 68

A Expert for the defense, correct.

Q And what you said is, "I'm an anatomic -- on line 5, page 5 -- pathologist. What that means, I think perhaps you have heard something about that work before, so I won't go into too much depth. But different than an MD who deal entirely with autopsies, a hospital based anatomic pathologist looks at basically any tissue that can be removed from a person and analyzes it under a microscope"; correct? You said that?

A I think that's probably a typo. I probably said "different than an ME," medical examiner.

Q It goes on and says, "If you've ever had a biopsy or a surgery, anything like that, that goes to an anatomic pathology lab and someone like myself will look at it under a microscope and make a diagnosis as to whether something is benign, malignant, inflamed, normal."

A Okay.

Page 69

Q And then you also describe how -- well, it goes on to -- that's your description to the jury in 2019 in the Bronx about what you do as an anatomic pathologist; correct?

MR. SLATER: Objection. You can answer.

A That's what I said at the time. My understanding is that the practice of pathology had been discussed with the jury before. I believe I was under that impression. So I gave sort of a general and high-level view of what an anatomic pathologist does. I could talk for an hour about the details, if we want to. But this is what I said.

Q You're under oath; correct?

A Yes.

Q You swore to tell the truth; correct?

A Yes.

Q And you did tell the truth; correct?

A Oh, yes, that's true.

Q You're a board-certified

Page 70

anatomic pathologist; correct?
A I am.
Q Also, in terms of patients as I understand it from looking at prior testimony of yours, you sort of team up with the doctor who follows the patient and sees the patient; in fact, as a gastroenterologist in the Benicar litigation, for example.
So there's another doctor that teams up with you who provides the clinical part; correct?
MR. SLATER: Objection. Mischaracterization. You can answer.
A Well, the way it works is, a pathologist doesn't ever procure or almost never -- I never procure my own specimen. So anytime that I'm looking at a biopsy or a surgical resection, it's either a surgeon or gastroenterologist, some other physician has collected that sample. And that other physician is the one who has been seeing the patient, talking with the patient and working on them.

Page 71

So by the time I get the sample, there's a care team. And I'm part of the care team, similar to the way a radiologist, you know, doesn't go out on to the street to pull them into the MRI machines. Another doctor refers them. So any patient that I see has, you know, seen a different physician and is working with another physician.
Q I think that's a correct way of looking at it. Part of the team, your role again as the anatomic or surgical pathologist is to look at the tissues, the specimens, you know, that kind of thing; correct?
A In the context of the patient, it would be inappropriate to just look it in a vacuum. In most instances, it's important to know the clinical history of the patient, presenting the symptoms and to synthesize both patient's clinical background and what I might see under a microscope.
Q And, Dr. Lagana, what you do is you prepare reports that again

Page 72

describe what you see under the microscope as you said; correct?
A That's the main way I communicate my results.
Q 75 percent of your practices are on that; correct?
MR. SLATER: Objection. You can answer.
A Or more. Certainly, there are times when a discussion is needed. And that could be an e-mail to a clinician or a phone call.
Q 25 percent of your work I guess is split between teaching, research and administrative tasks, maybe a little bit of legal work?
A Well, the legal work, I try to keep on nights and weekends. So my official time is for the most part clinical work, first and foremost; administrative work, which has increased over the years, and is continuing to increase; teaching and research.
Q In the clinical pocket, again, you're part of a care team;

Page 73

correct?
A Yes.
Q You're official role is to do the pathology report; correct?
MR. SLATER: Objection. You can answer.
A Yeah.
Q When you see patients, it's like one and done with your patients; correct?
MR. SLATER: Objection. You can answer.
A Well, that I definitely would not say is entirely correct, no.
Q Largely correct?
MR. SLATER: Objection. You can answer.
A What do you mean by one and done?
Q Well, how often do you follow patients from Point A to Point B to Point C? Aren't you doing your pathology role where you get specimens and not seeing patients?
MR. SLATER: Objection. You

Page 74

could answer.
A So really depends on the patient. There are some patients, I've seen their biopsies for years and years; for example, we have an active transplantation service at Columbia. So there are liver transplant patients who I've probably seen 20 biopsies from over the years, you know. So I do know -- I know their history very well. I know what they've had both clinically and pathologically.
Q It's just coincidental --
MR. SLATER: I'm sorry. He was not done talking. I don't think you realize it. But please don't interrupt him.
Q Were you finished?
A I wasn't finished.
So the patients who require frequent biopsies and especially the ones who have GI or liver problems, I am quite familiar with and do provide some continuity of care in that regard.
Furthermore, there are a lot

Page 75

of times where I'll look at a biopsy or a resection, and I'll feel the need to check a prior specimen. If we had a prior biopsy, you know, I'll want to know what was in that one. So I'll go back, and I'll look at that.
So it's not always a one-and-done type of thing; you know, there are certain times where it is one and done if someone has reflux, a gastroenterologist does an esophageal biopsy that shows reflux-related inflammation and nothing more advanced, no other issue. I probably would not make a mental note of that or feel the need to check something else about that.
So there are one-and-done cases. And there are cases where it's a long -- I mean there are patients that had been diagnosed and had biopsies for ten years.
Q The vast majority of the time where you're doing your pathological review, they're one and done; correct?
MR. SLATER: Objection.

Page 76

A That's the majority. I wouldn't say vast majority.
Q And you team up with a clinician who treats the patient, follows the patient, discusses things with the patient; correct?
MR. SLATER: Objection to the form. And I'm going to just state for the record, this is one of the multiple areas where counsel has continued to ask the same questions in the same areas over and over again which is not appropriate. It's contrary to the protocol in the rulings in this case and is going to have a significant impact on our decision as to whether to file a motion for a protective order at the conclusion of seven hours on the record by defense counsel.
MS. COHEN: We're also going to keep track of how many speaking objections are made. And we're going to count those against the time as well. I'm entitled to ask my

Page 77

questions, and I will. We'll call the judge.
Q You want to have the question read back?
A Please.
(The requested portion was read back by the court reporter.)
A Yeah. For the most part, that's true. These days in the electronic medical record era and people having access to their reports, sometimes they result themselves online. Traditionally and the way it's supposed to work is if a physician takes a biopsy or does a surgery, that's the physician who should be speaking with the patient and relaying the results that they got from the pathology report.
Q And that's what I want to ask you.
You're not actually conveying diagnoses to the patients; correct?
A Well, as I said, now that question has become much more complicated

Page 78

to answer than it would have been a couple of years ago before the health apps and that sort of thing. As of now, actually, a lot of patients are getting my report directly.
Q You're talking about communications, you and a patient verbally, meeting, discussing, assessing; that happens with a different doctor; correct?
A Almost always.
Q You're not the one giving cancer diagnosis to the patient; correct?
A It depends what you mean by giving.
Q Let me fix that.
Other than your report, which may have some commentary about the findings, you're not conveying cancer diagnosis in patients; correct?
A Well, I would disagree with -- I'm not sure I know exactly what you mean. I would say that when I make a decision of cancer, I have given the diagnosis of cancer for that patient.

Page 79

Q You're not in any way verbally communicating or doing anything outside of the report to convey cancer diagnosis to the patient?
A That I agree with, yes.
Q You expect other doctors -- whether it be, again, surgeons or gastroenterologists or other specialties -- to utilize your report, your findings and then go about meeting with a patient and conveying that to the patient; correct?
MR. SLATER: Objection. You can answer.
A The only issue I would take with that statement is that often, it's not a surgeon we're relying on. I could be a gastroenterologist. It could be many different members of the care team that are going to be tasked with acting on my report.
But I would expect that whoever recorded the procedure that resulted in the issuing of a report, that physician is responsible for interfacing

Page 80

with the patient and putting in place the proper care plan.
Q Fair enough.
So sitting here today, you cannot think of any time -- let me ask it this way.
Sitting here today, you have never made a diagnosis in any of your reports that you've done as a pathologist of an NDMA- or NDEA-induced cancer; correct?
MR. SLATER: Objection. You could answer.
A I don't know.
Q Have you ever used those words in a report?
A The etiology of a cancer essentially never goes into a report. So even if I diagnose a lung cancer, I don't say lung adenocarcinoma-smoking-related. It's just lung adenocarcinoma. So I couldn't say whether any of the cancers that I've diagnosed have been caused in part or in whole by an NDMA or not.
Q Super helpful. Thank you

Page 81

for saying that. Exactly my point.
You don't get into exactly the genesis or cause of the cancer; you just list the cancer in your report or what you think is consistent with cancer; correct?
MR. SLATER: Objection. You can answer.
A Can you ask the question again?
Q Yes. Again, I think you said it.
You said in your reports, you put down your findings, not the cause of the findings or the genesis of the findings; correct?
MR. SLATER: Objection. You can answer.
A I think there are two issues that are getting a little bit conflated here that I want to tease apart.
One is, as a pathologist, I'm an expert on pathobiology and pathophysiology. So knowing etiologies of cancer is certainly part of my

Page 82

practice and part of the knowledge base to be a good anatomic pathologist. In an individual case, we usually do not attempt to ascribe an etiology to an individual biopsy sample.
Q Let me ask it again.
So in your clinical practice when you're preparing your reports, putting down your diagnosis, you don't include etiology is what you're saying; correct?
A I may think about the etiology. I may know the etiology. But I very rarely write an etiology in a report.
Q And, again, you have never put in any report or any written assessment, pharmaceutical induced-cancer; correct?
A I have never used the words "pharmaceutical-induced cancer."
Q Or NDMA or NDEA-induced cancer; correct?
A Those wouldn't be terms I would put in a report.

Page 83

Q And sitting here today, you can't think of any time when you thought that something was NDMA or NDEA-induced; you can't come up in your mind of any instance where you thought that was the cause or genesis?
A I think a patient's exposure history to NDMA is not something that would normally be provided to me. It's not something that would typically enter my thinking.
Q That's exactly my point.
In your clinical practice, you have never addressed or dealt with the issue of NDEA or NDMA in terms of that being the cause or origin of a cancer; correct?
MR. SLATER: Objection. You could answer.
Q Or the etiology?
MR. SLATER: Objection. You could answer.
A Can you ask the question again?
Q Yes.

Page 84

Again, in terms of your analysis or assessment of the specimens you're looking at in any of the cancer diagnosis you've made, you've never in your mind thought, oh, NDEA or NDMA in terms of the etiology?
A Correct. In clinical practice, in a busy clinical practice day, that's probably not the sort of like thinking that I would entertain.
Q And in terms of the types of cancers that you diagnose, I think you said you diagnose liver cancer from time to time, not diagnosing, you make findings that are consistent with liver cancer; correct?
A That's a hair too fine to split. I certainly diagnose many cancers, including liver cancer. I'm a subspecialist in GI and liver cancer. So that means -- or a subspecialist in GI and liver pathology, I should say. So I frequently diagnose cancers of the esophagus, stomach, small intestine, colon, liver, pancreas and bile deducts.

Page 85

I also spend three months a year on a general surgery pathology service which exposes me to really almost any type of cancer. But common ones that I see would be breast cancers, lung cancers, cancers of the thyroid gland or head and neck and also prostate, bladder, kidney.
Q What percentage of your time of yours is on the surgical rotation?
A It can vary a little bit. Usually, it's about a quarter.
Q Total time of the year?
A Yeah.
Q And let me ask this question.
As a pathologist -- and I've seen a lot of these reports pathologists make -- when you have a suspicion of cancer of whatever type it is, you don't put down diagnosis of cancer; you put down whatever the finding is consistent with cancer; right?
MR. SLATER: Objection. You could answer.
A No, not necessarily.

Page 86

Q You tell me.
What verbs do you use? If we were to have access to your reports on your service and they were cancer-related, what is the verb you use?
A It depends what sort of cancer that we're talking about. But if we're talking about, say, a colon cancer and it was clearly a cancer, not I'm concerned it's cancer, I know it's cancer, then the diagnosis is invasive adenocarcinoma, then I would give it a degree of differentiation. I would comment on how deeply invasive it is. So that is very clear, a diagnosis of cancer.
Q But you're including -- again, the verbiage is talking about the findings; correct?
A Well, invasive adenocarcinoma, adenocarcinoma is cancer. That's just a technical way of saying cancer.
Q And, again, in terms of any of the times that you are either

Page 87

suspicious of cancer or listing something that is either a finding of cancer or as you said adenocarcinoma, you never put down etiologies in any of the reports; correct?
MR. SLATER: Objection. You could answer.
A I wouldn't say never. There are some specific cancers where knowing etiology is actually very important.
Q Give me an example.
A Sure. So head and neck cancer, for example, especially in the oral cavity. You can get head and neck cancer in the oral cavity from two main ways. One is cigarette smoking. The other is Human Papilloma Virus infection. And I can actually test for HPV infection. And it's important to know whether an oral cancer is HPV-related or not because the HPV ones respond very well to radiation, whereas the smoking and drinking ones don't. So it's standard of care for that cancer to say whether it is or is not caused by HPV.

Page 88

Q If you know about the HPV, is what you're saying?
A Well, we can test for it. So testing for it is part of my job.
Q So that would be an endogenous etiology; correct?
MR. SLATER: Objection. You can answer.
A No. It would not be endogenous. It would exogenous from outside. It's the virus. That would be the cause of the cancer.
Q And the cigarette smoking, if you're aware of that in the clinical history, you might list that? Do you actually put that in your report?
MR. SLATER: Objection.
A No, I wouldn't. I would just include the results of HPV testing, negative in that case.
Q So that's an example of where you might include an etiology if you're aware of it from a specimen or a test you conduct yourself?
MR. SLATER: Objection. You

Page 89

can answer.
Q Correct?
A Yeah, if I do the test myself and if there is a clinical benefit to including that data.
Q But other than that -- again, I think you said you won't say never -- but virtually at all times, you're not including an etiology; true? We looked at all your reports?
MR. SLATER: Objection. You can answer.
A Let me just think for a second. Yeah. I would say in most instances, I do not include an etiology in a report, in most instances.
Q And my question was, in virtually all instances other than the one example you came up with, you do not include an etiology? That's not your job; correct?
MR. SLATER: Objection. You can answer.
A Well, in the liver cancer world, we will often include an etiology

Page 90

of the chronic liver cancers, almost always caused by chronic liver disease, be that chronic Hepatitis C, B or alcoholic hepatitis. So we'll almost always include what the background liver disease is. I wouldn't necessarily say hepatocellular carcinoma due to chronic Hepatitis C virus. But I would say hepatocellular carcinoma, moderately differentiated, period; new line, chronic Hepatitis C stage, whatever, et cetera. So a lot of my liver cancers do have an etiology embedded in them.

Q. Yet, never, have you listed a drug or toxicity or impurity as an etiology; true?

MR. SLATER: Objection. You can answer.

A. I've diagnosed many drug-induced injuries in people. As I sit here today, I don't recall making a diagnosis of a drug-induced cancer or a saying, claiming that some cancer was specifically drug-induced.

Q. And, again, in terms of

Page 91

treatment -- well, let me ask this.

The phrase "clinical pathologic" or "clinical pathology" refers to what you're talking about where it's you and a team of other specialists who are the clinicians following the patient who team up; correct?

MR. SLATER: Objection. You can answer.

A. The term "clinical pathologic" correlation or "clinical pathologic" diagnosis, what that really is saying is that there are some diagnoses that cannot be made in a vacuum by a pathologist. And there are some that can.

But, for example, I'm an expert in celiac disease. And I can tell you exactly what celiac disease in the small intestine looks like. But there happen to be a few celiac disease mimics. So I might look at a specimen, and it looks exactly like celiac disease. But a patient actually is not sensitive to gluten. They had a different problem

Page 92

that is causing the same histology. So that celiac disease is always a clinical pathologic correlation.

Contrary, cancer, if I diagnose cancer, there's pretty much nothing that the clinician can tell me that would change my mind about that being cancer.

Q. You're giving your opinion about the findings in the specimen that you look at; true?

MR. SLATER: Objection. You can answer.

A. Well, I mean if I look at the slide and it's a malignant cancer, then that's what it is. And there's no other explanation for it.

Q. That's what your opinions derive from in your clinical practice, the slides and the specimen; that's what I'm saying; correct?

MR. SLATER: Objection. You can answer.

A. I'd say that's very narrow. And that's certainly not always the case.

Page 93

I think by what you said, there is a sort of cutout of the whole clinical part. It is not a pathologist's job to only do the pathology in a vacuum and ignore the clinical data. There are times when the clinical data is more important than others which is what I was sort of getting at there.

And the pathologist usually isn't the only one evaluating the clinical data. But, you know, it is -- ultimately, if there's anything in the patient's history that I need to know, it's my job to know it.

Q. That's a very important part of what you take into account then; correct?

MR. SLATER: Objection. You could answer.

A. The patient history?

Q. Yes.

A. Is important.

Q. Patient history, the patient factors in terms of cancer; correct?

MR. SLATER: Objection. You

Page 94

can answer.
A As far as diagnosis?
Q Right.
A Yes.
Q And, in fact, one of the things when we talked about differential diagnosis, that's something that obviously you're required to do in your clinical practice; correct?
MR. SLATER: Objection. You can answer.
A Putting together a differential diagnosis, a formal differential diagnosis, I would include it if I think there's doubt about the diagnosis.
Q So you have your report in this case, Valsartan. I think it's been marked as Exhibit 1 if you pull it up there. We'll come back to the deposition on some other points later. But you could put that aside for now.
But if you look at Exhibit 1, I want to just hone in on page 3 there. You're familiar with the word

Page 95

"methodology," of course; right?
A Yes.
Q That's something that you do in all of your patients; correct?
A Yes.
MR. SLATER: Objection.
A I have a systematic way that I approach cases, yes.
Q And that's something that you do in the few expert witness cases you were involved in; you know the importance of methodology too; correct?
A Yes.
Q In your last report, Benicar, we had a report and a deposition, one thing that was noted was that you did not cover in any way, the Bradford Hill methodology and differential diagnosis in your report; correct?
MR. SLATER: Objection. You could answer.
Q Do you recall that?
A I recall that being an issue, that I had not explicitly -- or a

Page 96

line of questioning anyway that I had not explicitly referenced Bradford Hill.
Q And Mr. Parker questioned you about that in your deposition. Do you recall that?
A Vaguely.
Q And Mr. Slater came back and asked you more questions about that. Do you recall that?
A Yes. Vaguely.
Q Did you ever receive or become aware of a Daubert motion that was filed? Do you understand what that is?
A Not entirely.
Q There was a motion filed to exclude you as a witness.
Did you ever get a copy of that?
A No.
Q Were you aware of that?
A I may have been, yes. I think I was aware.
Q In this report in Valsartan, you've included specific commentary about Bradford Hill?

Page 97

A Yes.
Q And was that in response to that Daubert motion? Do you know?
A Well, the Bradford Hill viewpoints are kind of standard epidemiologic viewpoints that we cover when we're in med school learning about differences between causation and association.
Now, I did not -- in the Benicar report, I did not specifically list them out. And that became an argument. So for the purposes of not getting into the same argument, I listed them here. However, there are things I would think about. Those are things that I thought about in the Benicar litigation before producing the report. And there are things I think about anytime when someone is talking about whether something is in association or causative relationship.
Q So you are familiar with methodology, differential diagnosis in the context of your clinical practice, as

Page 98

well as expert work; correct?
MR. SLATER: Objection. You could answer the question.
A I'm aware that one should have a method.
Q Are you familiar with what the other Daubert criteria are? Is that legal stuff you don't fully appreciate?
MR. SLATER: Objection. You could answer.
A I don't know.
Q One of the things you said here on page 3 of your report is, "I am basing everything stated herein on the basis of the methodology that I apply in my clinical and academic work."
Those were your words; right?
A Yes.
Q One of the things -- I know you just mentioned and we talked about before -- is association and causation. You agree -- and I'll read this quote -- "It's a foundational tenet of medical science that an association does not

Page 99

equal causation."
You agree with that; right?
MR. SLATER: Objection. You can answer.
A Yes. Certainly, an association is not definitive evidence of a causation.
Q And you said that before under oath, haven't you?
A I don't know. But I agree with it.
Q You agree with it.
So, again, here, Valsartan report, you say you're going to use the basis and methodology you apply in your clinical work; correct?
MR. SLATER: Objection. You can answer.
A Yes. And I did. I consulted Peer Review literature which is what I do in clinical work.
Q Let's look at the Benicar report which we marked over there. And I think it's that one right there.
A Okay.

Page 100

MR. SLATER: Just give me a second. Let me get to that. So now we're deposing him on the Benicar report?
MS. COHEN: Which exhibit is that?
A 4.
Q And you actually had a section called Methodology and Literature in the Benicar report. Do you see that on page 2?
A Okay.
Q Are you with me on that?
A I see it.
Q What you -- I take it again, your clinical methodology in 2017 is the same as you have now; correct?
A More or less, yeah.
Q Nothing has changed about that; correct?
MR. SLATER: Objection. You can answer.
A My clinical methodology?
Q Yes. We go back to what you said here. You said, the basis of the

Page 101

methodology --
MR. SLATER: Wait. I'm sorry. Valsartan or Benicar?
MS. COHEN: I'm going back to Valsartan, page 3 where it says, "I'm basing everything stated herein on the basis of methodology --
MR. SLATER: I'm sorry. Where are you reading from?
MS. COHEN: Page 3 of the Valsartan report.
MR. SLATER: Oh. You're in the middle of the sentence.
MS. COHEN: Yes, which we read before.
Q "I'm basing everything stated herein on the basis of the methodology I apply in my clinical and academic work."
We just read that; right?
MR. SLATER: Objection. Not accurately read.
A Could you read it again, please?
Q You could take a look. We

Page 102

just read it before. It's the same sentence. You don't disagree with that, do you?
MR. SLATER: Objection.
Q What you said there?
A I agree with what I said here.
Q And then if we go back to Benicar, because you had an actual section there a little bit more robust, if you will. So I want to ask you about it.
What you said there is, "The diagnostic approach I take to such cases is standardized."
And that's what you said again today; correct?
MR. SLATER: Objection. You can answer.
A We're talking about different things here.
Q Let me read this part.
MR. SLATER: Were you still talking before counsel interrupted you?

Page 103

THE WITNESS: Yes.
MR. SLATER: You could finish your answer.
A Okay. The Benicar litigation came with a number of actual cases that I investigated at the time. So what I'm describing at least just from a quick overview here is how I would approach a clinical case. So this is not -- I'm sure at some point in getting to review the literature, maybe.
But at least what I'm seeing here on page 2 is if I received a biopsy from a clinical case, this is the way I would approach it which is the same way I approached the clinical cases that came to me through that litigation. In this litigation, I haven't looked at any specific cases.
Q I think we agree with all that.
A Okay.
Q So let me unpackage that.
In your clinical practice as an anatomic pathologist or a surgical

Page 104

pathologist, what you're doing is looking at specimens; that's what you do; you look at slides, specimens, perhaps some bodies as you said, and that's how you make your determination; correct?
MR. SLATER: Objection. You can answer.
A That is the practice of surgical and anatomic pathology.
Q That's your practice; that's what you do; right?
MR. SLATER: Objection. You could answer.
Q Doctor?
A Yes.
Q And then when we get to in Benicar in 2016 in your report -- or 2017, you said, "The diagnostic approach I take to such cases is standardized, and is the approach utilized in my clinical practice, in connection with the studies I have authored in the Peer-Reviewed medical literature, and presentations given at major professional meetings. I start with the review of very basic,

Page 105

clinical information (generally limited to the presenting symptom; e.g. diarrhea). I then begin my slide review;" right?
A Remains true.
Q And that is how you do your clinical work; correct?
MR. SLATER: Objection. You can answer.
A Yes.
Q And that's how you do your expert work; correct?
MR. SLATER: Objection. You could answer.
A You know, expert work is not one size fits all. So it's different -- I've done expert work where they sent me a slide and say, did the original doctor missed diagnosis of cancer? If that were the case, I would apply the methods specifically listed here which apply to looking at slides and looking at clinical cases. By here, I mean in the page 2 of the Benicar report.
Part of my practice, though,

Page 106

is also to keep abreast of medical literature and need to produce medical literature. And so if someone were to ask me, as in this case, to look into the issue or issues around NDMA or NDEA, contamination of Valsartan, you know, I wouldn't start looking at a glass slide. I would go to the PubMed. And the methodology I used was a research methodology, essentially, of looking at both statements from regulatory agencies and looking at original Peer Review medical research. And that's the approach I would take if I were writing a paper on a particular topic. Or as new things come up in medicine, that's how I keep abreast.

Q You obviously never looked at any clinical information, slide reviewed patient information in Valsartan; correct?

MR. SLATER: Objection. You could answer.

A That's correct.

Q And in terms of what you

Page 107

just described, what you described before, answering a general question of general causation of cancer in humans, you've never done that as part of your clinical practice, have you?

MR. SLATER: Objection. You could answer.

A Sorry. What is the question?

Q Yes.

When you go through the pathology evidence that you do in your cases as part of your clinical practice, you're obviously looking at data, clinical data slides, patient information; correct?

A Yes.

Q You've never in terms of your clinical practice answered a general causation question like the one that Mr. Slater put to you that kicks off your expert report; correct?

MR. SLATER: Objection. You could answer.

Q It's not what you do?

Page 108

A Well, I integrate that information; for example, you know, it would be a pretty lame pathologist who didn't know that cigarette smoking causes lung cancer. And there are more specific examples like the one we talked about with respect to HPV-related cancers of the head and neck.

But it would be totally inappropriate to Mr. Jones who has a biopsy to get into some treatise on etiology as part of the report on Mr. Jones's cancer. That's not part of my practice.

Q Right. But that's what I'm saying.

This answering of a general causation like the one Mr. Slater posed to you that kicks off in your report is not what you do in your clinical practice; true?

A No. I think that's mischaracterizing it, I think. Every pathologist -- I'm an expert in pathobiology. So pathologists know about

Page 109

the causative factors of cancers and inflammatory illnesses. It's a major part of that. But it doesn't go in a report, usually. But not going in a report is different from not using that information or knowing that information.

Q Let me ask a couple of follow-up questions.

You agree you don't put that in the report; correct?

MR. SLATER: Objection. You can answer.

Q You just said it.

A In most instances.

Q You agree you don't put it in the report in most instances; correct?

A Correct.

Q You haven't written any papers about it; correct?

MR. SLATER: Objection. You can answer.

A About causation?

Q Yes.

General causation of cancer like we have in this case, you've never

Page 110

written a paper on that topic; true?
A No. I don't think that's true.
Q You're welcome to tell me which ones are general causation literature.
A Give me a moment, please, to review. Reference 7.
Q Van Treeck, is that the one?
A Yes.
Q And that's the hepatocellular carcinoma, reveals novel distinct biological features?
A Yes.
Q And you believe that is a general causation article?
A Yes.
Q We have it. And I'm happy to discuss it with you later.
What else?
A 12.
Q Metastatic breast cancer revealed by a systematic analysis.
A Enrichment of kinase fusions in the SR wild-type, yeah, that deals

Page 111

with causation of cancer.
Q Do you believe that that is an opinion on general causation like the type that was framed in this case to you by Mr. Slater?
MR. SLATER: Objection. You can answer.
A I'm giving you papers that I've been involved in dealing with causation of cancer.
Q Right. Let me ask.
12 is about 4,854 patients that addresses a specific patient like the clinical findings we're talking about, like the methodology that's in the Benicar. There are patients here; right?
MR. SLATER: Objection. You could answer.
Q Mr. Slater likes to laugh at every question. So I assume that doesn't bother you. Doesn't bother me either.
A I'm afraid I don't totally understand where we're --
Q Do you understand the difference between general causation and

Page 112

specific causation? I'm happy to explain it to you.
A I certainly have thoughts on that. But let me hear how you're interpreting it first.
Q I think specific causation would be a situation where you're assessing medical records, clinical features, specific data points, specific pathological information.
A Okay.
Q Like you describe in your Benicar report.
Isn't that what this article with the 4,854 patients is?
MR. SLATER: Objection.
Q Specific issues of patients?
MR. SLATER: Objection. You can answer.
A It's pathobiology of cancer.
Q Any other articles that -- the question that I posed to you is, have you written about general causation of cancer?
MR. SLATER: Objection. You

Page 113

can answer.
Q Can this etiology cause this type of cancer?
A Well, yeah. I mean No. 12 certainly is satisfactory there.
Q You think 7 is too, the one we pointed to first?
A Possibly.
Q Not sure, but maybe?
A It could be argued, one way or the other.
Q It might be.
A We can do that. 12 is; 14; 17; 19 is related to causation of neoplasia, non-malignant neoplasia; 21; 29; No. 6 under case reports.
Q Does that involve a patient?
A Yes.
Q So that wouldn't be case-specific as opposed to general commentary on causation?
A Well, I mean -- generally, any case report is published because the thought is, it might be generalizable at least to other patients.

Page 114

Q You understand what epidemiology is; right?
A Yes.
Q And you're not an epidemiology expert, are you?
MR. SLATER: Objection. You can answer.
A So are we putting aside the last question?
Q No. I'll re-ask it in a minute.
A Okay. No. 6 on selected published abstracts.
Q Have you gone back and read any of these before today?
A Any of my papers?
Q Yes. The ones that you're looking at now.
A Okay. I think that covers that.
Q Any other business where you've written about or published about general causation, like a question that was posed in this case, and you listed the ones that you think are part of that?

Page 115

MR. SLATER: Objection. Foundation. You can answer.
A Yeah. I answered with respect to Peer Review publications that I've authored or coauthored that deal with the issue of causation of cancer.
Q My question was about general causation. You remember that; right?
MR. SLATER: Objection.
A Yeah. I'm not sure, you know, where -- anything I've published is because I would expect it to be generalizable, at least to some extent.
Q And just because this will be part of the record later, you understood my question --right?-- when I asked you?
MR. SLATER: Objection.
A I answered it to the best of my understanding. I understood something. I answered that thing. That is not what you asked, then I didn't understand you. If that was what you asked, then I did.

Page 116

Q I didn't ask you about -- I asked you about general causation.
What I mean by that is, in this case, what you told me a little while ago is that you didn't look at any patient-specific information, no medical records, no slides, which is what you do in your normal practice; correct?
MR. SLATER: Objection. You can answer.
A I didn't look at any specific patient data, correct.
Q And the articles you cited to me, at least some of them, look at patient-specific data?
A I don't see how the fact that they might have used specific patients as a basis for their conclusions, how that would relate to whether or not a conclusion is generalizable or not.
For example, saying that we looked at 4,000 patients and we found X percent had this mutation and we think this maybe driving their cancer, that is

Page 117

pathobiology of cancer, that's causation of cancer. And presumably, those are not the only patients on earth with that situation.
Q That's an important part of your analysis; that is what happened in those patients; correct?
A Those patients provided the basis of the analysis that took place.
Q Other than this report that we've marked as Exhibit 1 in this case, have you ever rendered a causation opinion based purely on articles and general information without patient information as an anatomic pathologist that you are?
MR. SLATER: Objection. You can answer.
A Could you repeat that?
Q I'll try it again.
Never once in real life, not in a litigation, have you rendered a causation opinion based purely on articles and not with regard to patients?
MR. SLATER: Objection. You

Page 118

can answer.
A I base opinions on causation strictly from articles many times. But I have not written a report to that effect.
Q So what I said was true? You never rendered an official causation opinion based on articles without regard to patients?
MR. SLATER: Objection. You can answer.
Q And patient information.
A Well, I mean without regard -- this is all -- I'm a doctor. So, of course, I'm thinking about how this would impact a patient. That's the framing that I used to understand this problem, is, would this do something or nothing to a patient. And if so, would that be a good, bad or neutral thing.
Q I asked the question, never once in real life, not in litigation have you rendered a causation opinion based purely on articles and not with regard to patients. And you said I have not written a report to that effect; correct?

Page 119

MR. SLATER: Objection. You can answer.
Q Is that what you said?
A Not that I could think of at this moment.
Q So I took it one step further.
You've never given an official causation opinion, report or otherwise, based purely on general articles without patients and patient information?
MR. SLATER: Objection. You can answer.
A Sure. I mean it's not on general articles. It's on specific articles that did look at patients largely and also experimental animals. Those are the reliances that were provided and are included here. That's the basis of my opinion, Peer Review medical literature, as well as guidelines and consensus statements from World Health Organization, IARC, FDA.
Q We're going to go through

Page 120

all that in a minute.
But my question again is, this is the first time you've done this, that is rendered an official opinion like this without looking at patient information?
MR. SLATER: Objection. Foundation. You can answer.
A I mean I definitely looked at patient information. All the epidemiologic studies deal with patient information. I just didn't look at my own data. I didn't treat any of these patients.
Q That's not what you do in real life, is it?
MR. SLATER: Objection.
A In real life?
Q As a doctor, as a clinical pathologist, an anatomic pathologist, you do not do what you did in this case; true?
MR. SLATER: Objection. You could answer.
A Well, I read literature of

Page 121

this type in my daily practice. It's important for me as I said to know etiologies and to know causation. So reading these things, forming opinions is all very much part of what I do.
As far as making an official report, I mean that doesn't go into a patient report. In the literature that I write, I might include things that I found, and I certainly do include things that were found in the Peer Review literature, some of which I can't off the top of my head mention every -- you know, every citation included in any of my research.
But, you know, the discussion portions or the introduction portions of a research paper often summarize literature similar to what's done in this report. Now, there probably are some patients that I encountered also in that Peer Review literature. So if you want to drive some -- draw some bright line there, I'm not sure that it really is applicable. But I don't

Page 122

think -- you know, I haven't produced a document like this outside of this.
Q This is the first time in this litigation; correct?
MR. SLATER: Objection. You can answer.
A Yeah. I've dealt with the issue of causation in other contexts but not as a stand-alone.
Q And I think I asked you this before.
You certainly do not hold yourself out as an epidemiologist; correct?
A Again, I understand epidemiology. I learned epidemiology in medical school. I am aware of epidemiologic concepts. And I've worked with and published with epidemiologists.
Q Have you ever said under oath that you certainly do not hold yourself out as an epidemiologist?
A I do not know. I am not a professional epidemiologist per say. I am familiar with it.

Page 123

Q Let's go ahead and mark this one as an exhibit too.
And while we're getting that out, you're a member of CAP?
A Yes.
Q You've been a member for how many years?
A I don't remember. Maybe ten.
Q You're familiar with their expert witness guidelines?
A I don't know that I've seen them.
Q Regardless, I'm sure that you would agree as an expert witness, you should only venture into areas where you're qualified; correct?
A Yes.
Q You would not again offer opinions in areas where you're not qualified or it's outside of the realm of what you know and do in your practice; correct?
A Well, I wouldn't offer opinions outside of things that I know

Page 124

about.
Q And you understand the importance as an expert witness of being honest and unbiased and not being an advocate; correct?
A Yes.
(The above-referred-to document was marked as Exhibit 7 for identification, as of this date.)
Q And here is Exhibit 7, which I'll give you. And this is --
MR. SLATER: A different version that I have. Oh. You just put the sticker on it. Got it. No problem.
Q On this one, just going back to page 342 on this epidemiology --
MR. SLATER: Just one question, counsel. I'm just not sure and I don't remember because the Benicar litigation was several years ago. But this is marked as protected information, this transcript. So I just want to make sure -- I'm not sure how you got this or whether or

Page 125

not there was any violation of the protective order in the Benicar litigation.
MS. COHEN: I think it was filed.
MR. SLATER: It was attached to the Daubert motion?
MS. COHEN: I think so.
MR. SLATER: I think Susan Sharko might not be excited if confidential or protective information is being put on the record.
MS. COHEN: I'll state on the record, it's online, publicly available.
MR. SLATER: Perfectly fine. Just looking out for everyone's interests.
Q Page 342?
MR. SLATER: 342?
MS. COHEN: Yes.
MR. SLATER: Just give me a second to turn to that page.
Q And the question was on line

Page 126

2, "You certainly don't hold yourself out as an epidemiologist?"
And what did you say back then under oath?
A "I do not."
Q And you said as far as being a part of the College of American Pathologists, you're not familiar with the expert witness guidelines?
A Not that I recall.
Q Would you say you agree with the points of --
MR. SLATER: If you're reading from something --
MS. COHEN: No. I'm going to ask if he understands this.
MR. SLATER: So you're not going to show him the document that he's not familiar with?
MS. COHEN: Right.
MR. SLATER: You're just going to read from it?
MS. COHEN: Yes.
MR. SLATER: I don't have it. So I can't verify what you're

Page 127

saying is accurate.
MS. COHEN: No. My questions are just in general. I want to just ask him whether he agrees with this statement.
Q That an expert witness should possess current experience and ongoing knowledge in the area in which you're testifying. You agree with that?
A Yes.
Q You agree that as an expert, you should testify fairly -- as fairly and objectively as possible?
A Definitely.
Q And as an expert witness, do you agree that you should review the facts in a thorough, fair and objective manner and not exclude any relevant information?
A I do.
Q Now, we talked about before that -- and we have your invoices which we can go ahead and mark as an exhibit.
(The above-referred-to document was marked as Exhibit 8 for

Page 128

identification, as of this date.)
MS. COHEN: These are the ones that counsel for plaintiffs have provided to us. We'll mark them as a composite exhibit.
MR. SLATER: This will be Exhibit 8, I guess, the invoices?
MR. SANJABI: It is, yes.
THE VIDEOGRAPHER: We are now going off the record. The time is 11:41 a.m. Eastern Time.
(A short recess was taken.)
THE VIDEOGRAPHER: We are now back on the record. The time is 11:57 a.m. Eastern Time.
MS. COHEN: So we're back on. And we'll shoot to get to the next part. We're going to take a break at one o'clock for everybody so they know that's coming. And I did pull out the invoices while on the break. And I think we have them all together now.
Q Let's see. Exhibit 8, I'll give that to you.

Page 129

A Okay.
Q I'll just tell you, Doctor, that counsel provided these to us as all of the invoices to date. So I just want to have you confirm that. And then I'll ask you a few questions as well.
A Yes. This looks like everything that I've billed to date.
Q And this shows us -- again, I know the date on the first page, although you can't see it here, I think when we pulled it up electronically was 2020. Is that your understanding as well?
A Yes.
Q And I think we know from our discussion before in Benicar, you did your report I believe in 2016, and at your deposition in 2017. I want to make sure those dates are correct. Does that sound right?
A Sounds generally right. I don't recall specifically.
Q November 30th, 2016 was the report. And then we have the deposition

Page 130

taken in 2017, February 7th, 2017.
So, again, this is now just a few years later. An hour discussion with Mr. Slater kind of kicked things off in August 2012. You agree with that?
A Sounds right.
Q In terms of the rates, I think you clarified that the rate was $600 an hour; is that correct?
A That is.
Q And that's for all review information, review of everything; in the deposition, you charge $5,000 a day?
A $6,000 per day.
Q In the Benicar report on page 2, which I believe is Exhibit 4, let's see, your compensation at that time was $500 an hour. So that's gone up $100; is that right? My sophisticated math.
A If that's what it says here, then, yes, it's gone up.
Q Page 2, looks like that's increased by 100. I thought it was going to be a very significant increase going

Page 131

from $1,000 about an hour for testimony to about $5,000 per hour.
A Yeah. It's not that much. Yeah.
Q It's gone up, though?
A It's gone up, as does everything.
Q You said here back in 2017 that you have not previously testified at court or in deposition at any lawsuit.
So was it at that time that you had not given any testimony at all?
A Right.
Q Are you doing anything to advertise your availability or willingness to do expert witness work?
A I think I might have signed up for one or two directories.
Q And was that like SEAK? Is that one of them?
A I don't know. To be honest, I haven't gotten any referrals for many years. I don't recall.
Q How did you and Mr. Slater first meet?

Page 132

A I think Mr. Slater knew one of my colleagues. And he was looking for a pathologist. And I was recommended.
Q And then you got involved in the Benicar litigation?
A Yeah.
Q And that litigation -- again, the Benicar litigation had to do with, would you agree -- let me ask you.
What do you think it had to do with, the Benicar litigation?
MR. SLATER: Objection. You can answer.
A Some percentage of patients who take Benicar and other sartans. But mainly, Benicar, have a terrible reaction to it where they get diarrhea, malabsorption, they lose tons of weight, many of them end up hospitalized with dehydration from all the diarrhea. So really, a terrible celiac-like illness that thankfully seems to be away relatively quickly when they stop taking the drug.
Q And celiac disease, celiac

Page 133

disease research is one of your primary areas of research; correct?
A Yes.
Q And, in fact, in the report, you talk about how celiac is one of your areas of focus, and inflammatory conditions of the small intestine are also one of your major research interests; correct?
A Definitely.
Q And that's still true; right?
A Absolutely.
Q Now, this has -- let's see -- you're billing up to the date of the report, July 6th?
A Correct.
Q How much time have you spent since the report? An estimate is fine.
A 15 hours.
Q Getting ready for today?
A Yes.
Q And what did you specifically do to get ready for today?
A I re-read my report, perhaps

Page 134

more than once. I re-read key literature studies.
Q Are those some of the ones you have here on the table?
A In the -- yeah.
Q If they're key, you'd have them here on the table; is that right?
A I believe so, yeah.
Q And we'll probably get those marked or at least identify them before the end of the day.
A Okay.
MR. SLATER: Objection to the form of the question. I didn't want to talk over you.
THE WITNESS: Okay.
A So, yeah, reviewed my report, reviewed my literature or the literature that I had collected as part of my research, had some discussions with Mr. Slater.
Q Did you get together to meet?
A No.
MR. SLATER: You mean in

Page 135

person?
MS. COHEN: It's not that important.
Q Do you talk by phone?
A We talked by phone.
Q And today, you two walked in together.
That was just a coincidence?
A I saw him pull into the parking lot and said hi.
Q How much in total, how many hours have you spent? Do you know?
A No.
Q How much time have you spent on your report itself, that is writing it?
A I think most of the last bill was spent writing the report. So that would be 33 and a half hours. I didn't -- some of this, other than the December bill, could have been report-related, or it could have been literature review-related.
Q Did you have to consult with anybody about any issues or questions?

Page 136

A No.
Q You didn't seek any information from any colleagues?
A No.
Q There's an oncology group at Columbia; right?
A Yes.
Q And are they people that you consult with on patients?
A Yes.
Q They treat patients; correct?
A Yes.
Q Terrible question.
On the patients for whom you write your pathology reports, the oncologists would be involved to treat the patients; correct?
MR. SLATER: Objection. You can answer.
A If it's a patient that requires oncologic medicines. If they need surgery, they might go to a surgeon instead.
Q Are there particular ones

Page 137

that you collaborate on patients or does that just happen just some other way?
A It's kind of luck of the draw, I would say. Maybe not luck. I don't have a specific relationship, whereas some oncologists, you know, specifically refers to me or vice versa.
Q You don't hold yourself out as an oncologist; correct?
A No.
Q And there's nowhere we could look online, either with the expert witness groups that you signed up for or Web sites or anywhere on the Columbia Web site that says you're a cancer specialist; correct?
MR. SLATER: Objection. You can answer.
A So there are some people who refer to the surgical pathology of cancer as oncologic pathology. And certainly, I am an oncologic pathologist. I'm an expert in pathology of cancer and pathobiology of cancer. Oncologists, medical oncologists, I say medical

Page 138

oncologists because this would refer to a radiation or surgical oncologist. But a medical oncologist is an expert at the drug regimens that are given to patients with cancer. So that, I am certainly not. I have a little bit of knowledge there. But I am not a medical oncologist. You could say I'm an oncologic pathologist.

Q So I understand that you think you have -- you consider yourself to have in the field of pathology, expertise in cancer?

A Yes.

Q And that's what you said already today. I'm not going to argue with you about that, nor am I going to agree with you on that. It's a fact. And we'll leave it alone.

But is there anywhere that you've held yourself out publicly to the world on a Web site as an expert witness, anything where you say I'm a cancer expert?

MR. SLATER: Objection. You

Page 139

can answer.

A Well, I'm definitely an expert on cancer diagnostics.

Q But --

A And cancer biology.

MR. SLATER: Can you please let him finish?

Q I already said --

MR. SLATER: Counsel, you're doing it again. Please let him finish his answers.

A Whether it says on my faculty Web site or something, those words, I don't know.

Q That's what I'm asking you.

A I don't know.

Q Is there anywhere in the world that you hold yourself out as either having a special expertise of cancer oncology?

A I think we're maybe getting a little confused about medical oncology versus cancer in general. So medical oncology, again, I am not a medical oncologist. And I would never claim to

Page 140

be. As far as expert on cancer, I mean I certainly am. I'm an expert in the diagnostics of cancer, pathobiology of cancer.

Q And, again --

A Et cetera.

Q Are you finished?

A Yes.

Q So I basically said we're not going to argue about that.

What I'm asking you is, is there anywhere you've held yourself out on a Web site, publicly as someone who has expertise in cancer or oncology?

MR. SLATER: Objection. You can answer it again.

MS. COHEN: Well, he keeps changing the answer.

MR. SLATER: Counsel, you're getting argumentative.

MS. COHEN: I'm not.

MR. SLATER: Well, you know what, counselor, you are. And I don't think you're listening to his answers.

Page 141

MS. COHEN: No. I am.

MR. SLATER: So you're withdrawing the last question?

MS. COHEN: Yes.

Q I'm asking you again, is there anywhere -- it's the same question, but you keep changing the direction.

MR. SLATER: Counsel, that's the third time --

MS. COHEN: Do you want to call --

MR. SLATER: No. I'm just asking you not to be argumentative with him. I think I've been very polite today. I don't think your suggesting that I'm not being polite is fair.

MS. COHEN: I'm not always fair. But I try to be.

Q Is there anywhere that you've held yourself out publicly on a Web site or in advertising or anywhere else as having cancer oncology expertise?

MR. SLATER: Objection. You could answer.

Page 142

A I don't know. Maybe.
Q Now, in the expert witness groups that you've now signed up for, how many of them are there?
A I don't know; two, maybe.
Q And you don't remember the names of them?
A Correct.
Q You're listed as part of them to offer up your expert services?
A Correct.
Q Could you provide the names of the companies to Mr. Slater after since you can't remember them now following this event today?
A I don't know.
Q Do you get paid by them?
A If I recall correctly, I might have been referred one case through one of them many years ago. And in which case, I would -- I don't know if they paid me or whoever hired me paid me. Certainly not in recent memory, have I gotten a case from them. So I'm just not sure I could produce that information.

Page 143

Q Do you know what you listed yourself as in those groups? Do you list yourself as a pathology expert?
A Probably, yes. I would assume so. I don't remember.
Q And is it fair to say that you do not list yourself as a cancer expert?
MR. SLATER: Objection. You can answer.
A I wouldn't say that that's fair. I mean I am an expert on cancer diagnostics, pathobiology of cancer. At least, you know, a good portion of my time is spent diagnosing cancer, staging cancer. As I mentioned before, working on the proper ancillary tests to do for patients with cancer. So I certainly do not think it is in any stretch, in any way a stretch to say that I'm not an expert on cancer.
Q Why doesn't the Columbia Web site call you an expert on cancer?
MR. SLATER: Objection. You can answer.

Page 144

A May I review what the Web site says?
Q Yes.
A Okay. So the Columbia web site says I'm a surgical pathologist. And surgical pathologists are an expert at cancer -- and that is a fact -- where the cancer diagnosticians with subspecialty expertise in GI and pathology. And that would encompass inflammatory and malignant neoplasms.
And then if you go to the next page, page 4, it does include liver tumors as an area of expertise and also hepatocellular carcinoma.
Q Liver cancer?
A Liver cancer.
Q Does it say anywhere cancers?
MR. SLATER: Can you let him finish, please?
A It doesn't list other cancers. But as I said, I'm a subspecialist in GI pathology. So GI neoplasms, their biology, their

Page 145

diagnostics, their prognosis, there's staging, there's theranostics, meaning what markers they express that might guide treatment. I'm damn sure an expert on all of that. And I'm not going to, you know, negotiate that word.
Q Liver is what you're saying?
MR. SLATER: Objection.
A No. Liver, GI, which includes esophagus, stomach, small intestine, colon, anus, liver, pancreas, bile deducts.
Q So if we look at your curriculum vitae, let's take a quick look at that.
A Sure.
Q We already talked about how it's a different version from the Benicar version. But we'll focus on the Valsartan one.
You have that in front of you? I think it was marked as Exhibit 3.
MR. SLATER: You're going to question him on the Valsartan case, not the Benicar case?

Page 146

MS. COHEN: Valsartan CC.
A I have it.
MS. COHEN: So I didn't say that, no.
MR. SLATER: So I should go back to the Benicar report?
MS. COHEN: If you want to.
MR. SLATER: Counsel, I'm asking you. I got confused. Did you say we're on Benicar or Valsartan?
MS. COHEN: No. We're on the CV in Exhibit 3, Valsartan. But we may go to the other one too.
MR. SLATER: It's your time. It's your use of your time.
MS. COHEN: Thank you, Adam. I appreciate that.
Q If we look at page 1 of this, this gives your training and education; right, Doctor?
A Correct.
Q And, again, obviously, it's all focused on pathology; correct?
A Well, medical school is not pathology-specific. That was a broad

Page 147

medical education that included rotations in internal medicine, surgery, everything.
Q And then it gets into pathology; correct?
A Yes.
Q And we don't see anything about cancer on page 1, do we?
MR. SLATER: Objection. You can answer.
A That's a gross mischaracterization. Medical school had quite a bit on cancer. My residency and fellowship training both were heavily focused on cancer.
Q Does it say the word "cancer" on page 1?
A It doesn't say a word about any specific disease on page 1.
Q Does it say anything about oncology on page 1?
A What diseases are mentioned on page 1? I don't see any.
Q So it included oncology?
A Cancer is included in

Page 148

gastrointestinal, liver and surgical pathology and anatomic pathology. All of these include cancer.
Q I'm just asking you the words on there.
Is it cancer oncology?
A Whether or not the word is there is meaningless. It's included in this.
Q You can't look at the page and tell me whether cancer oncology is on there?
A The words are not on there. But the training encompassed it. And as I said, I just have to -- it's an important point to me personally.
Q And then on page 2 where it talks about organizations, Peer Review, are you on any boards that are specific to cancer?
A Boards?
Q Yes.
A Boards specific to cancer?
MR. SLATER: Objection. You can answer.

Page 149

Q Or an organization. I'm trying to figure out what, if any --
MR. SLATER: Objection. You can answer.
Q Members of foreign organizations, Peer Review, any of those specific to cancer on page 2?
MR. SLATER: Objection. You can answer.
A Okay. Almost any of these will deal with cancer in part. So, you know, papers -- well, other than perhaps -- well, actually, all of them deal with cancer to varying degrees, some quite a lot. And I review papers related to cancer all the time.
Q There are organizations that are cancer and oncology; correct?
MR. SLATER: Objection. You can answer.
A There are ones that are specific to oncology that would not have an interest in inflammatory conditions, yes.
Q So there are specific cancer

Page 150

in oncology. We could take out any of our cancer biology experts and people like that or oncology experts. There are specific organizations.

I'm trying to ask, are you on any specific organizations related to cancer oncology?

MR. SLATER: Objection. You can answer.

A Yeah. I mean I'm not in any organization that is exclusive to cancer. I'm in many organizations that deal in large part with cancer.

Q Sure. I'm asking you a different question, though. And I can certainly pull out our cancer expert's CV if we need to.

Are you in any of those organizations?

MR. SLATER: Objection. You haven't listed them.

A I think I answered that.

Q So you're not on any of those?

MR. SLATER: Objection. You

Page 151

can answer.

A I'm in societies and organizations that deal in large part with cancer. College of American Pathologists, for instance, puts out the guidelines for the diagnosis of many types of cancer. And I'm involved with those organizations. But I mean if -- I'm not a member of any societies that deal exclusively with cancer.

Q Do you ever attend their meetings?

A College of American Pathologists?

Q No. The oncology meetings, cancer meetings.

A The meetings I attend, I frequently attend USCAP and the CAP, well, most often, the CAP. And they deal in large part with cancer. But I have not gone to American Association for Cancer Research.

Q Or oncology meetings, you don't go to their meetings, I take it?

MR. SLATER: Objection. You

Page 152

can answer.

A Well, there would be no reason for me to go to a medical oncology meeting. I don't prescribe any medicines.

Q How about a surgical oncology meeting? Do you go to any of them?

A No.

Q How does it work at Columbia? Just tell me about the way it works. There's a pathology department, and that's where you're housed, if you will: You're a member of that; right?

A Yes.

Q There's probably a surgery department as well; correct?

A There is.

Q Now, where are the cancer specialists located? Are they in their own group?

MR. SLATER: Objection. You can answer.

A So I mean cancer care, monitoring cancer care is really a

Page 153

multidisciplinary endeavor. So you have medical oncologists who -- I'm inferring that you're referring to when you say cancer doctors, or maybe I'm wrong there.

Q No.

A You said medical oncologists who are a division of the division of internal medicine at Columbia. You have surgical oncologists who are housed under the department of surgery. You have radiation oncologists who I think are their own department. I don't think they're under radiology, and you have radiologists who specialize in cancer diagnostics.

Q Under Columbia University, there's the -- on the Web site, there's a whole section on cancer, and there's the cancer center, the cancer center which is designated by The National Cancer Institute. Are you part of that cancer group?

A I don't know. I work with them all the time. I'm not sure if pathology is included. If pathology is

Page 154

included, I would be part of it. But I don't know if pathology is included.
Q Does Columbia University Herbert Irving Conference Cancer Center, HICCC, which again is set up by The National Cancer Institute --
A I did not say that.
Q -- recognized as a comprehensive cancer center by The National Cancer Institute?
A Okay. I agree.
Q Are you part of that, are you listed there?
A I don't know.
Q Do you participate in any of their meetings of things?
A Definitely, yes.
Q Would it surprise you if we looked at this and your name didn't come up?
MR. SLATER: Objection. You can answer.
A I really don't know. I don't know if there are any pathologists listed. If there are, I would expect

Page 155

probably to be one of them. But I don't know.
Q And are there at Columbia what's called cancer biologists or cancer researchers who specifically look at issues of causality in cancer?
A I presume so.
Q Have you ever talked to any of them about the issues in this case?
A No.
Q Have you ever talked to them about causation issues for any of the patients?
A It doesn't sound implausible. But as I sit here today, I don't have a specific recollection.
Q And, again, could you name any of the cancer biologists or cancer researchers that are known to be part of this -- where it said the Herbert Irving Comprehensive Cancer Center? Do you know any of the people there who are on the cutting edge on the study of cancer biology?
MR. SLATER: Objection. You

Page 156

can answer.
A I'm sure the medical oncologists are listed: Dr. Schwartz, Dr. Manji, Dr. Drake. Yes. I know the medical oncologists. As far as the people who do only research and do not see patients and are cancer researchers, those are not people I would likely interact with closely. I am aware of some of them.
Q Do you read their research?
A Sometimes.
Q Do you know whether they have published or had anything -- doing any research on the issues of nitrosamines, Valsartan, anything related to this case?
A To my knowledge, no.
Q When Mr. Slater first got you involved in the case and we just looked at those, pull it back up, at the invoices. Let's see. Starting in August, August 12th of 2020, and we talked about sort of the initial question that was framed for you.

Page 157

And I want to ask, were you asked to assume anything in the case?
A Not to my recollection.
Q When you said you read over your report, you said maybe a couple of times in recent days?
A Yes.
Q Did you read it last night?
A I did.
Q Did you read it this morning?
A No.
Q How many times did you read it yesterday?
A Probably twice.
Q And, again, I know I asked you about epidemiology.
You're also not a biostatistician; correct?
A Right. I understand biostatistics. I have a functional knowledge of it. But I am not a biostatistician by any stretch.
Q And I mean probably everyone in this room, we all have a different

Page 158

functional knowledge of things.
But I'm asking you specifically, do you hold yourself out as an expert in biostatistics or as a biostatistician?
A No, not an expert or a particular biostatistician. I have a working knowledge, functional knowledge of biostatistics. And I do use that knowledge to analyze medical literature as part of my normal practice.
Q And you're not a cancer biologist; correct?
MR. SLATER: Objection. You could answer.
A Again, I have a deep knowledge of cancer biology and cancer -- I'm an applied -- I have a deep knowledge of cancer biology, cancer physiology. I am not a researcher devoted entirely to cancer biology.
Q No.
You've told us today what your cancer experience is; correct?
A Certainly not. I haven't

Page 159

told you all of it.
Q No.
You told me about some of the articles you identified for us; correct?
A I did tell you that.
Q You told us about how as part of your work as an anatomic pathologist where you sometimes make diagnoses that you incorporate into the report; correct?
A Almost every day. I diagnose probably thousands of cancer cases.
Q And of the thousands of cancer cases, what percentage are liver or hepatocellular?
A A very rough estimate. I would say perhaps 20 percent, 15 to 20 percent, mainly because the incidents of liver cancer is much lower than some other common cancers like colon cancer or prostate cancer.
Q How many pathologists do what you do at Columbia, that is a part

Page 160

of -- I know you're obviously an associate professor.
How many do what you do as part of the anatomic pathology group?
MR. SLATER: Objection. You could answer.
A There are about 24 anatomic pathologists at Columbia. There are five or six of us in the -- five of us active in the GI and liver subdivision.
Q And so anytime there's a GI issue, they tend to come to one of you five?
A Yes.
Q And the same would be true -- what are the other areas within -- if you're in --
A What other sub-specialties?
Q Yes.
Is breast cancer a special one?
A Partially, yes.
Q Breast cancer patients would tend to go to those people?
A Tend to, yes.

Page 161

Q What other areas, if you know?
A Neuropathology is a separate area; non-neoplastic kidney is another area; skin, inflammatory conditions of the skin anyway, go to a separate area; hemopathology, blood cancers.
Q Different people deal with that; right?
A Yeah. I might see them. If I see a case, let's say leukemia or lymphoma, I'd say this is not for me.
Q You send those to the subspecialists?
A Right.
Q How about bladder? Would other people deal with bladder?
A No. Bladder and prostate go to the general surgical pathology service. And this is very detailed minutia of how our department is. But those go to general surgical pathology which I rotate on for three months of the year. So diagnosing bladder cancer, I probably do 50 to 100 cases a year;

Page 162

prostate cancer, probably the same; kidney cancer, probably less because just the incident's less; 25 kidney cancers per year.
Q How many pathology specimens typically are you looking at? And if you can't tell me because you don't keep track of those, it's fine to estimate.
A Roughly speaking, I look at around 6,000 a year. And I'm on service 75 percent of the time. So we could do the math.
Q And you're saying 20 percent -- I may have written this down.
What percentage are cancer of the 6,000?
A Variable. To be in the ballpark, I would say 10 percent.
Q And then of the 10 percent, 20 percent are of the liver?
A Again, ballpark, that's correct.
Q Colorectal are in its own group?

Page 163

A It's part of GI which I do several ones a year as well. This again gets into some minutia. If there are too many cases of GI, then things go to surgical pathology. I diagnose a lot of colon cancer a year, probably 100 cases a year, maybe 50, something like that.
Q Other than the blood cancers, are there any cancers that you absolutely will not get involved in?
MR. SLATER: Objection. Lack of foundation. You could answer.
A Primary brain cancers.
Q Now, also, before I go back to the point I started with on this path was about assumptions, I do want to ask you, you're not a pharmacologist; correct?
A Correct.
Q You're not a toxicologist; correct?
A Correct.
Q You're not an internal medicine hypertensive expert?

Page 164

MR. SLATER: Objection. You can answer.
A I'm not an expert on the management of hypertension.
Q Before this litigation, getting involved in this litigation in the fall of 2020, I take it you didn't do any research on NDMA, NDEA or Valsartan?
MR. SLATER: Objection and asked and answered. You can answer. She's only asking if you did the research, not the reason for which you did the research.
A Okay. Then the answer is yes.
Q Let me ask it this way.
Before this litigation, meaning Valsartan, and meeting with Mr. Slater in the fall of 2020, did you ever do any research outside of the litigation on NDMA, NDEA or Valsartan?
MR. SLATER: Objection. Counsel, you asked this question before. I mean I'll let him answer again because it's one question. But

Page 165

you're retreading ground now repeatedly. You can answer.
MS. COHEN: And I'll just state I disagree on the record.
A No.
Q Now, on the issue of assumptions, again, you understand as an expert witness, your job, your role is to give opinions; correct?
MR. SLATER: Objection. You can answer.
A As long as we're saying that they're scientific or medical opinions to a reasonable degree of medical certainty, then yes.
Q And that's what you understand is important as part of your expert report, your report and your testimony; correct?
MR. SLATER: Objection. You can answer.
A Yeah. I mean I considered my role to look through the medical and scientific literature to form an opinion and then to express that opinion.

Page 166

Q And as you said, with a requisite degree of certainty, with a reasonable degree of medical certainty?
A Yes.
Q Your job is not to come in here or in your report and speculate; correct?
A Yeah, correct.
Q It would be improper to guess; correct?
MR. SLATER: Objection. You can answer.
A And that's a broad hypothetical. But generally speaking, I would try to avoid any guesses.
Q And you're not -- again, you think it would be improper to assume things that you don't know to be true; correct?
MR. SLATER: Objection. You can answer.
A You know, it's such a broad question that it's hard for me to give -- we assume many things throughout the normal course of doing business. So I

Page 167

don't think I assume anything beyond -- you know, for example, if I download something from the IARC Web site, I assume that I'm getting what the IARC meant to upload. But for all I know, Russian hackers could have changed it. So I can't say, oh, I've made zero assumptions. Of course, I made normal assumptions like any person would. But I don't think I made any assumptions that are outside of the realm of how I normally go about my business.
Q What I'm asking is, let's put it in the context of your clinical practice and how you do things.
When you write one of your reports based on your specimens and review of specimens, you're not going to put in there assumptions about what may or may not be in there; correct?
MR. SLATER: Objection. You can answer.
A Well, that's an interesting point. I can't really agree with that. There are times in a surgical pathology

Page 168

report where speculation, or even one might say guesses do sometimes come into reports. If there is a specimen that is not entirely diagnostic, it's not really my job to say I don't know what this is, period. I would go through a standard workup which might include going to certain colleagues, doing additional testing, show it to colleagues, maybe even send it to another institution and to have them take a look and I still don't have an answer and no one I come in contact with has a firm answer, then I would write a differential diagnosis which is, you know, some thoughts on what it could be. It's not based on nothing. It's not wild speculation. It's based on previous cases I've seen or descriptions in the literature or what have you.
To some extent, it's a homework assignment for whoever sent the specimen because now they need to go and think about, okay, Dr. Lagana suggested Diagnosis X, Y and Z, is there a blood test for this. And I might say I

Page 169

wouldn't do this blood test, I would do this imagining, something like that.
Q Would you ever say in a report I assume this finding is cancer or would you say in my opinion, it's cancer?
A If something is diagnostic of cancer, I wouldn't -- I mean I guess it's implied that it's an opinion. But I would just write hepatocellular carcinoma, period; invasive adenocarcinoma, period; sphenoid cell carcinoma, period.
Q So I'll get back to that in a minute.
But have you ever had a situation where you've turned down a legal case -- and I know you didn't get many from your signing up of these organizations. But did you ever turn down a legal case and say I'm not the right person for this, it's not my area of expertise?
A Yes.
Q And you would do that; right?

Page 170

A Yeah. I have done that.
Q What type of case have you turned down?
A Let me think. It's not terribly infrequent that I'll get asked to look at a case that is not really like cytology cases, for example. I don't practice cytopathology. So it's not too infrequent that I'll get asked to look at, say, like a cytology specimen from the pancreas because I do practice pancreatic pathology, but not in the fashion that a cytopathologist would. That would be a common request that I would turn down.
Q I'm sure you said from time to time, I'm a pathologist, this is far afield and outside my area of expertise; correct?
MR. SLATER: Objection. You can answer.
A Usually, when I get asked to look at a case, it is reasonable for a pathologist to look at a case. Occasionally or often, questions will

Page 171

come up in the case where I don't have an opinion. And I have to express. And I don't have an opinion on this.
Q Did you say that to Mr. Slater about anything? Did you say there are certain areas I can't get into this litigation, I can only cover pathology?
MR. SLATER: Objection. You can answer.
A Yeah. I mean there are parts of this litigation that we've discussed that I've tried to familiarize myself with. But I have definitely expressed to Mr. Slater that they would be better covered by a different expert.
Q For example, if you're giving a differential diagnosis or applying a methodology, you have to understand how the methodology in the differential diagnosis works clinically; correct?
MR. SLATER: Objection. You could answer.
A Sorry. Can you rephrase?
Q In order for you to do a

Page 172

Bradford Hill diagnosis, give a differential diagnosis, apply a methodology, you have to have the grounding and the expertise in that area; correct?
MR. SLATER: Objection. You could answer.
A So I'm still not entirely sure I understand.
Q Do you agree -- we've already looked at the earlier reports, your differential diagnosis in this case, and we talked about Benicar is grounded in your clinical expertise; correct?
MR. SLATER: Objection. You could answer.
A Well, in this case, I haven't issued a differential diagnosis. I haven't looked at any specific cases with respect to this. In the Benicar case, sure, then I looked at individual patients. And for those patients, I could put together a differential diagnosis.
Q Let's put aside the

Page 173

differential diagnosis. Let's talk about methodology.
A Okay.
Q Your methodology and your opinions and your report is basically clinical experience; correct?
MR. SLATER: Objection. You could answer.
A It depends on how strictly you want to define clinical. In the issuing of a pathology report for a particular specimen, usually, I don't need to go back to the medical and scientific literature to issue that opinion, although there are times when something is very rare where I do have to go to the primary literature in valuing it. So that's on one level.
On a higher level, being a pathologist, it requires me to be -- and I am -- an expert on pathobiology. And so to acquire that expertise, I do stay abreast of the medical literature and scientific literature. And I do read it as part of my routine practice.

Page 174

Q Do you recall earlier today when you told me that the basis of the methodology you applied in this case was your clinical work?
MR. SLATER: Objection. You can answer.
A I don't recall saying that exactly. I certainly said that with respect to when we were reading from the Benicar methodology because again, that was evaluating specific patients.
Q You don't remember saying that in this case?
A Clinical work informs it.
Q Do you understand that -- well, let me ask this.
When you do an expert witness report like this, do you take it seriously?
MR. SLATER: Is that a serious question?
MS. COHEN: Yes, absolutely.
MR. SLATER: If he takes this seriously?
Q Do you take the expert

Page 175

witness report in this case seriously?
A Yes.
Q And do you take it as seriously as the testimony you're giving?
A Yes.
Q And everything you say in it is true; correct?
A To the best of my knowledge, yes.
Q Let me have you look at page 11, going back to the assumption part. I asked you before whether you assumed anything in this case. And I think what you said is you may have made some assumptions, but you wouldn't assume something that goes to the core issue?
MR. SLATER: Objection. Lack of foundation.
A I said that we can't get through life in any endeavor without making some assumptions. And I tried to make no more assumptions than I would normally make to get through life.
Q On the key issue that was framed for you that was given to you to

Page 176

answer, you wouldn't make assumptions on that; you would actually give opinions; correct?
MR. SLATER: Objection. You can answer.
A With respect to the key issues, I would look at the literature and statements from regulatory agencies, like WHO, IARC, FDA, as I did and come to an opinion, yeah.
Q Page 11 of your report, let's look at that for a minute.
A Okay.
Q And obviously, as you say, cancer is a multifactorial disease. And you list many things that can contribute to carcinogenesis; right?
A Yes.
Q Then you go on to say, "Therefore, for any patient who develops cancer and is known to have a significant exposure to a probable human carcinogen (the levels documented above constitute a significant exposure in my opinion), it should be assumed that the carcinogenic

Page 177

exposure at least increased the risk or contributed to the subsequent cancer unless there is a convincing body of evidence to suggest that the carcinogenic insult is null with respect to the specific cancer in question."
Is that your opinion?
A Yes.
Q And you don't have any cite there, do you?
A No.
Q And, again, what's your definition of significant exposure? What's the basis for it?
A Well, the significant exposure would vary depending on what the carcinogen is. But this statement is actually not super controversial. Basically, if you're looking at -- is cigarette smoking associated with whatever cancer, general baseline, it's reasonable to suspect that it is.
And, in fact, cigarette smoking is associated with lots of cancers. But then there are some cancers

Page 178

which are proven through the research not to be affected by cigarette smoking. And so, fine, we accept that.

HPV is another great example. HPV can cause cancer in the mouth like we discussed and the anus. Similar cancers arise in the esophagus. And for many years, there was concern, is HPV causing these esophageal cancers. And it had to be disproven that it was not. So now we know it does not.

Anyway, I think if you're asking me what level is a significant exposure to NDMA and contaminated Valsartan, is that the question you want me to address?

Q No.

My question was -- you had no cite.

And I'm asking you, what is your definition and the basis for the words "significant exposure"?

MR. SLATER: Which question is it? Sorry. It seemed like there was a few questions. I object. You

Page 179

can answer.

A It depends on what the exposure is.

Q So it's not an absolute answer there; it depends on the exposure; right?

A What is a significant exposure? Yes, certainly.

Q And you gave me two specific answers: Cigarettes and HPV?

MR. SLATER: Objection. You can answer.

A Yeah. I mean -- right. Radiation is another example. Having a lung chest x-ray is okay; having 1,000 is not.

Q You say next, "The crucial point is that we start from the assumption that exposure to a human carcinogen contributed to carcinogenesis in a patient with a cancer unless there's convincing evidence to the contrary."

Now, you don't have any cite there; correct?

A That's right.

Page 180

Q That's your opinion; correct?

A That's my opinion.

Q You said I think about the prior sentence, and I want to ask you, you don't think it's very controversial. Do you think this sentence is not controversial either?

MR. SLATER: Objection.

A Well, with respect to NDMA, you have a compound that is a known mutagen, well-known mutagen as defined by IARC, cohort of concern where it's -- capacity to cause mutation. We know exactly how it does it, by alkylating DNA and causing methylguanine which is one of the main drivers of mutation in cells.

So if someone had an exposure to a drug, to a substance, that was causing -- that was a known mutagen, then I think -- and someone then develops a cancer, one would at least have to be very suspicious that the known mutagen, which messed up their DNA, contributed in part or largely to their cancer.

Page 181

Now, it may be that some cancers have nothing to do with this. And the literature could maybe eventually show that. But, you know, there's never been an experiment where we gave humans massive doses of NDMA because it would be wildly unethical.

Q So my question was, as this sentence, do you think that this is controversial or not?

MR. SLATER: Objection. You can answer.

Q What you said there?

A Let me read it again. It could be controversial.

Q You want to go back to the prior sentence and tell me whether you think the prior one is controversial now that you've had a chance to read it again?

MR. SLATER: Objection. You can answer.

A It's hard for me to speculate on what other people might read into my words. So maybe I shouldn't have

Page 182

said it's not controversial. I don't know whether it is or is not. I guess you have to ask a lot of different experts, what they think.
Q And you haven't run those two sentences by any cancer experts, have you?
A I am a cancer expert. But I haven't asked anyone else to read it.
Q What I mean by that, any cancer biologist, any epidemiologist, any oncologist? Have you run that by any of them?
A I haven't run the report by any of them, other than Mr. Slater.
Q One of the things you say in your report -- and I'm sorry to jump around here -- speaking of controversy, on page 5 --
MR. SLATER: Where are we now? In the same report?
MS. COHEN: Yes.
MR. SLATER: We're on page 5?
MS. COHEN: Yes.

Page 183

Q There's a sentence here that caught my attention. It says -- bottom paragraph, it says, "If one of these mutations causes the cell to become immortalized, then that can be the start of a cancer."
There's no citation there; correct?
A That's the basics of cancer biology. But I didn't cite anything, no.
Q Do you believe that one mutation can cause a cell to become immortalized and start cancer?
A Yeah, certainly. It depends -- it doesn't always happen that way. It's not that once a mutation happens, you have to get a cancer. There are various ways in which the body may be able to correct that error, that mutation, if we call it a mutation error. But that is the basis of how tumors begin. The mutation causes a cell to become immortalized. And it starts reproducing, reproducing. If the body fails to stop it, then that is the start

Page 184

of a cancer.
Q Is it your opinion to a reasonable degree of medical certainty that one of these mutations, one mutation can lead to cancer?
MR. SLATER: Objection. You can answer.
A Well, there are a lot of examples of cancers that are caused by one mutation.
Q So the answer is, yes, you believe one mutation can lead to cancer?
A Yeah. Not that it always does, not that every cancer only has one mutation. There's a lot of data here that we're drilling down to one very narrow question. But on that very narrow question, can one mutation cause a cancer? Yeah.
Q And you can't give us any cite to that; you just believe that to be true?
A Well, CK mutations in the gastrointestinal stromal tumors are a well-known example; the BRAF V600

Page 185

mutation in melanoma, in some colorectal cancers. Those are point mutations. And that one mutation certainly is a main driver of the cancer. BRCA1, PROP1 mutation, breast ovarian cancers. This is not rare where one mutation drives a cancer.
Q But have you ever given any talks, not on pathology, talks on cancer and cancer biology, cancer causation, anything like that?
MR. SLATER: Objection. You can answer.
A I'm sure talks that I've given have dealt with those issues. I don't know if any of them were specifically and exclusively on those issues.
Q So you may have been talking about pathology issues, and something related to cancer came up?
A Yeah. You can't really separate pathology and cancer this way. Cancer is a major concern of pathology. If there was no cancer, you know, we'd

Page 186

have maybe 10 percent of the pathologists that we have.
Q But etiology of cancer is not part and parcel of what you do every day? We've already discussed that; right?
MR. SLATER: Objection. You can answer.
A Well, I want to make sure we're clear on that point. I said I don't include in the etiology in a report for an individual patient in most instances. And that is true. But knowing the etiology of cancers and what causes cancer, what's the pathobiology of cancer from both the population level down to a molecular level is definitely part and parcel of what a pathologist needs to know.
Q But you don't always know the pathobiology, nor the etiology of cancer when you're writing your reports, do you?
MR. SLATER: Objection. You can answer.

Page 187

Q You couldn't; right?
A It depends how high up you want to go with that question. Do I know an etiology for every cancer I diagnose? No. But I'm aware of the molecular mechanisms behind any cancer I would diagnose. So in a narrow level, the answer usually is yes. On a broad level, it's sometimes yes, sometimes no.
Q Because as you say on page 11, we've looked at this before, "Cancer is a multifactorial disease. Permissive genetics, environmental exposures, epigenetics, random chance, bad luck all contribute to carcinogenesis."
You don't know what's happening with people in all of those areas, do you?
MR. SLATER: Objection. You can answer.
A I haven't cited to a lot of those areas. I don't necessarily have a complete picture of all of them.
Q I want to just quickly -- you said you make cancer diagnosis 6,000

Page 188

times a year; correct?
MR. SLATER: Objection. You can answer.
A I believe I said I examined around 6,000 specimens per year.
Q I'm sorry.
And 10 percent of cancer, that's 600?
A Yeah. I think that that's directionally right.
Q So about 600 patients a year.
You can't possibly know the multifactorial issues that you just raised in your own report for those 600 patients, can you?
MR. SLATER: Objection. You can answer.
A Yeah. I mean again, it depends on -- it depends largely on how wide or narrow you want to make that question. It's really not a question I can answer in that context. There are things I know and things I don't know.
Q And the factors that you

Page 189

listed there are just a small part of the real multifactorial set of issues that can cause cancer; right?
A I wouldn't say that genetics environment, epigenetics and chance constitute a small part. I would say that probably constitutes a large part.
Q You mean the broad swaths you describe in there?
A Yes.
Q Everybody has bad luck?
MR. SLATER: Objection. You can answer.
A Yeah. I mean as I say, cancer is a multifactorial disease. I listed some of the most important factors here, some of which I might know, some of which I don't know when I diagnose a particular patient. But it is important for a pathologist to have a working knowledge of all of these things at a high level at least.
Q And how do you get the working knowledge? You're not talking to the patient; correct?

Page 190

A Yeah.
Q So you look at medical records?
MR. SLATER: Objection. You can answer.
A Well, I mean I look at the patient medical records and the medical and scientific literature.
Q But in terms of, you said here, it's important for a pathologist to have a working knowledge of these things at a high level.
And I'm asking, in your given 600 patients per year of cancer, 20 percent of which are of the liver, the ones that we've talked about, again, working knowledge would come from either discussion with the referring doctor, doctors treating the patient, Number One; Number Two, the medical records; right?
MR. SLATER: Objection. You could answer.
A That's not always the case; you know, for liver cancers, I might look at the benign liver next to the tumor and

Page 191

see features of alcohol, cirrhosis, for example. So then I can get the information I need right off the slide. Other times I might talk to the submitting physician. I might read the patient's chart. I might go to the medical and scientific literature. Any of those things would be not out of the standard way to do things.
Q But from your perspective, just so we're clear before we move off of this, in terms of the factors, the ones you list here -- permissive generics, environmental exposures, epigenetics and random chance -- are the top ones for you? Those are the top factors; correct?
MR. SLATER: Objection. You can answer.
Q That's why you put them in your report?
A Yeah. I think those are probably the most powerful predicters of cancer development.
THE VIDEOGRAPHER: We're now off the record. The time is

Page 192

1:01 p.m. Eastern Time.
(A lunch recess was taken.)
THE VIDEOGRAPHER: We are now back on the record. The time is 1:43 p.m. Eastern Time.
Q Thank you, Doctor. Welcome back after lunch.
A Thank you.
Q We'll just pick up. Just a couple of questions still lingering from before that I want to go back to before we go forward. And that's on page 11 of your report. I don't know that I ever got an answer from you about what your definition of significant exposure is. Can you tell us?
A Sure. Are you asking in a general sense or as it relates to NDMA?
Q Well, you said, "Therefore, for any patient who develops cancer, and is known to have a significant exposure to a probable human carcinogen."
I'm talking about in that sentence, what are you referring to?
A Well, significant would

Page 193

depend on the carcinogen.
Q So you don't have any parameters; you're just saying whatever it is in a given situation?
MR. SLATER: Objection. You can answer.
A Well, I have plenty of parameters. But the parameters would be different if we're talking about -- depending on the carcinogen in question. If you want to go to NDMA specifically, the dietary literature seems to show a fact that around 100 nanograms per day, the FDA has set their maximum allowable amount at 96 nanograms per day. So I mean anything above the FDA's maximum allowable would strike me as significant exposure.
Q What do you have as the FDA's maximum allowable?
A 96 nanograms per day in a pill.
Q So basically, the purpose of this page of your report, when you use the words "significant exposure" related

Page 194

to NDMA, you're talking about anything over 96 nanograms?
A To the extent that this sentence wasn't specifically about NDMA. And as I said, the specifics of what is significant would depend on the situation. I mean as far as NDMA, even the FDA maximum allowable is an interim maximum allowable. We can live with that for now. The goal is to get to zero because it's a carcinogen. And there is no known safe intake amount. But certainly, 96 nanograms or above is significant. Less may be significant as well.
Q But for the purpose of this when you use significant, I think you already gave the answer, you're using the 96 nanograms by the FDA, and anything above that would be significant?
MR. SLATER: Objection. You can answer again.
Q Would you say that?
A Anything above that is definitely significant. I'm not ruling

Page 195

out the possibility that less is significant.
Q But sitting here today, you're using 96 as significant?
MR. SLATER: Objection. You could answer.
A I think it's a reasonable shorthand for the time being.
Q One other question about something from earlier.
I think you'll agree with us that in terms of the etiology of cancer, you can't diagnose or know that from looking at a slide or specimen; true?
MR. SLATER: Objection. You can answer.
A No. I said I wouldn't agree with that.
Q Do you think you can tell the sources and using the multifactorial from looking at the specimen?
MR. SLATER: Objection. You can answer.
A Well, you said it as a rule that you can't identify the source of the

Page 196

etiology of a cancer by looking at the slide. There are many instances in which you can, not all instances, but it's not a blanket statement that I would make, one way or the other.
The aforementioned HPV-related cancers, I can usually tell just by looking at the slide, whether they are or are not. Liver cancers, I can almost always tell what the cause of the liver cancer was by looking at the slide; you know, lung cancers, you might find an emphysematous lung in which case it would indicate cigarette smoking. So there are many times in which -- including common situations which you can certainly diagnose the cause or know the etiology of the cancer.
Q There are certain instances where you can, but there are many instances where you cannot; correct?
A Yeah. There are both instances where you can and instances where you can't.
Q If you talk about

Page 197

environmental exposures, genetics, random choice, you wouldn't be able to discern those using your list from looking at a slide?
MR. SLATER: Objection.
A Well, as I just mentioned, a lot of the environmental exposures can be figured out by looking at the slides. So that one, yes. Whether -- the person's genetics, there are certainly some tumors that are related to genetic syndromes and have a specific histologic phenotype which I can diagnose. Epigenetic changes, there are certain types of colon cancer, for example, that are thought to be caused by epigenetic phenomenon which do have a characteristic histologic appearance which I could recognize. So I would just avoid blanket statements in that regard because there are different scenarios.
Q What about let's say, No. 4, random chance, bad luck? You can't piece that together to discern from looking at a slide, can you?

Page 198

MR. SLATER: Objection. You can answer.
A I can't tell you how many times I've looked at this slide and thought, this poor person, that's really an awful lot.
Q Right.
But what I'm asking you about --
A At least in that scenario.
Q And I think what I understood you just said is that there are some instances where there's a specific marker, if you will, a specific pattern on the slide, and there, you can tell an etiology; right?
A Yeah.
Q There are many instances where you just cannot tell looking at a slide, you have to piece together the clinical, pathological points that we made earlier, consulting with another doctor, looking at the medical history; right?
A Both of those are scenarios,

Page 199

yeah.
Q Now, obviously, your report, which was signed off on July 6th, we're going to accept that as July 26th, you still stand by everything in it; correct?
A Yes, other than the reference issue that we -- the citation issue that we addressed.
Q What you said about that is you wanted to add a cite, not remove a cite?
MR. SLATER: Objection.
A Well, the citation that is -- I cited to the wrong Jakszyn paper in that -- I think it's No. 36. And I meant to cite to the one that we provided.
Q You're not backing off of the original 36, are you?
A Well, the original 36, I think I used for a different context. And so in whatever other context I used it, I still stand by that, that usage. It's just where I used it on whatever page that was, I meant to cite a

Page 200

different article there.
Q Right. Understood. It was in the wrong place.
But you still stand by that original 36 as being an important article; correct?
A Let me see what it is. I remember the author because of the citation. But let me see what the article is. Yeah. I mean this is one of many articles that I considered, was of some importance.
I mean really, there are -- I'm not so sure that there's one article that blows any of the others away. It's a weight of evidence approach where I looked at all the relevant literature. And they all contributed, one way or the other, to my understanding of the issue.
Q How many of the articles that you relied on were dietary ones as you described it?
A Pretty good number. If you want to know an exact number, we can go through them.

Page 201

Q It's okay.
A A decent proportion.
Q I was going to say, would you agree that the vast majority of the articles you cite to are dietary ones that you talked about before?
MR. SLATER: Objection. You can answer.
A Vast majority, I think, might be a little bit of an overstatement. I think dietary studies certainly provide a good -- a good portion, some significant portion of the basis of my opinions. But those aren't the only evidence.
I mean we also have industrial exposure evidence. We have what is -- we have what could be considered almost an ecological type study where they were looking at the urine of patients in China with cancers of the esophagus. Then we have experimental models in animals. And we have statements from regulatory agencies.
Finally, we have some, at

Page 202

least preliminary data in humans related to drugs and I think the Al-Kindi article, for example, where they were looking at the incidents of neoplasms in Valsartan patients before and after the FDA recall. I think that's a really important article.
Q We're going to go through all those.
Sorry. You're still answering?
A Yes. The main gist of that article was, it's very interesting to me because the relative risk of reporting neoplasms associated with Valsartan is, went from 1.7 pre-announcement to like 7-point-something post-announcement. So the author said, oh, my God, these people panicked. And they started reporting neoplastic adverse events because of news media or whatever. But it's very striking to me that there is a 1.7 relative risk before the announcements were made. So that meant the patients who were using Valsartan were 70 percent

Page 203

more likely to report a neoplastic adverse event compared to other ARB users. So I think that's a really scary number. And I mean as a doctor, it scares me.
MS. COHEN: Move to strike the part that's not responsive.
Q Let's look at in your report, page 3, if you will. So if we look at your report and take it in pieces, if you will.
A Sure.
Q It's 33 pages.
The first, we start with the introduction and the key question which we talked about earlier.
And then this background that covers part of page -- well, it covers page 2.
A Okay.
Q Tell me if you agree with me on that.
MR. SLATER: Objection. You can answer.
A I agree that page 2 seems to

Page 204

deal predominantly with background information.
Q Page 3 talked about again the methodology that you're going to apply in this case, as we already talked about, about six lines down. Then we get to the background section next, starting at the bottom -- halfway about page 3.
And the first sentence is, "NDMA and NDEA are volatile organic compounds known as nitrosamines, found in certain foods, cigarette smoke, water, and other sources as is germane to this discussion, certain medications."
And then you cite to References 2, 3 and 4; right?
MR. SLATER: Objection. Lack of foundation. Inaccurately read. You can answer.
Q I'm sorry. Do you not have foundation for this? Do you feel not qualified --
MR. SLATER: My objection was to you not reading the report accurately, asking to confirm the

Page 205

report was accurately read.
Q Do you feel qualified to speak to this sentence?
A The sentence as you read it, yes.
Q You can read it right there?
A Yes.
Q If I skip the parens?
A Yeah.
Q Certainly, you can look at that.
MR. SLATER: Objection. Lack of foundation.
Q And if we look at page 34, which is where the citations are, and Cite 2 is the article by Sörgel. I assume you read that one?
A Yes.
Q And you read all the articles that are cited herein?
A I did.
Q Let's get that one pulled out, if we can. Just for reference purposes, just so we're all on the same page, some of these articles, you cite to

Page 206

in multiple places; is that correct? If you look at page 7, just so you know where we're going on this, page 3. Then we also cite to the same article on page 7. I want to make sure we're all tracking this.

MR. SLATER: What article are you talking about?

MS. COHEN: I'm going to hand it to you. This is the Sörgel article which we're going to mark as 9.

(The above-referred-to document was marked as Exhibit 9 for identification, as of this date.)

MS. COHEN: I'll give a copy to the doctor. Do you need this one, Clem?

MR. TRISCHLER: If you have it, great. If not, don't worry about it, Lori.

Q So first of all, on page 3, where we started, you're citing to this -- for the proposition that NDMA, NDEA are volatile organic compounds found

Page 207

in various sources; correct?

MR. SLATER: Objection. You can answer.

A Yeah. I think I probably used this reference to relate to the part that it was found in Valsartan.

Q But, again, the sentence here doesn't distinguish between 2, 3, and 4; it basically says, the sentence I read, and you cite to this article?

MR. SLATER: Objection for multiple reasons, including argumentative. You can answer.

A The sentence makes various claims. And they are backed by the References 2, 3, 4 of which this is one.

Q So this is Article 2, and it's listed there -- right there after the first sentence. Then on page 7, if you look over that one where you cite to it again. And here, it says-- I'm going to start at the beginning of that one.

"The German central pharmacy (German's FDA equivalent) collected Valsartan pills from various

Page 208

manufacturers. They found between 3,700 ng per pill to 22,000 ng per pill in pills using the API produced by ZHP."

And your sentence is, "This paper equated a pill of Valsartan as being similar to smoking a package of cigarettes as far as cancer-free from NDMA."

Did I read that correctly?

MR. SLATER: Objection. Lack of foundation.

A "Cancer risk NDMA."

Q Let me try it again.

Package of cigarettes as far as cancer risk from NDMA, and you cite to this; right?

A Yes.

Q First of all, you're not an FDA regulatory expert; correct?

A Correct.

Q And you -- I take it, you are not an expert on the German Central Pharmacy which is the FDA equivalent; correct?

A This is what I understood it

Page 209

to be.

Q I'm just --

A I studied the organization -- I haven't studied the organization in particular detail.

Q Have you even heard it before this litigation case?

A The German Central Pharmacy?

Q Yes.

A Not that I recall.

Q This is obviously something new to you.

But am I correct that you're citing this sentence about a pill of Valsartan as being equivalent to smoking a package of cigarettes?

MR. SLATER: Objection. You can answer.

A Could you repeat the question?

Q So you see No. 2, that's a reference right at the end of that paragraph?

A Yes.

Q The sentence that you cite,

Page 210

reference to that is this paper equated a pill of Valsartan as being similar to smoking a package of cigarettes as far as cancer risk from NDMA. That's what you said in this article; right?
A Yes. That's what I said.
Q Can you show me where in this article it says that?
A Okay. It's going to take me some time to find, but sure.
Q Before you embark on that, let me ask this question.
Did you re-review all the articles you cited from your report to get ready for today or did you just again not re-review them all, stand by the articles that you had cited?
MR. SLATER: Objection. You can answer.
A I certainly re-reviewed a number of them. I don't think I re-reviewed every single one.
Q Did you re-review this one?
A Not to my recollection.
Q So if you can look at this,

Page 211

tell me where you got that statement.
A Sure. Okay. Well, the first relevant portion I see here is in Table 5, the 53.8 parts per million -- not Table 4. It's on Table 5, I guess. But let's look at page 399, Section 3.4, Tablets Tested. 53.8 parts per million and highest dose, which is 320 mg, around 20-some-odd thousand nanograms per pill. Package of cigarettes has about 17 to 22,000 nanograms of NDMA. So it's in that range.
Q The article itself doesn't make that statement, though, does it?
A Equate to the cigarettes?
Q Yes.
A I don't see it now. It may be in here. I don't see it there now but does give that amount of NDMA.
Q Right.
But in terms of the statement that this paper equated a pill of Valsartan similar to smoking a pack of cigarettes as far as cancerous, those words are not in this article, are they?

Page 212

A I'd have to look some more to see if that's in there or not specifically.
Q Look at page 404 under the conclusion. And, again, I could have missed that. I will state that on the record. I'm sure Mr. Slater will agree I missed things before. But this to me is the only reference to the cigarettes on page 404 under 5, talking about a reference to a paper reducing nicotine in cigarettes.
A Well, two possibilities. One is that I forgot the reference or messed up the reference there or that I just extrapolated the fact that they showed 20-some-odd thousand nanograms of NDMA which is a massive amount per pill with the fact that it's -- that's about what's in the package of cigarettes. So it's possible that I wrote that badly. I'm not totally sure. Or maybe it's in here. And we just haven't found it yet.
Q You would agree a statement like that, which is pretty salacious, if

Page 213

you will -- let me strike that because I'm getting a laugh across the table.
MR. SLATER: I didn't laugh, counsel. For the record, I did not laugh.
Q A pretty serious accusation that a pill is the same as smoking a package of cigarettes, I mean you want to be careful about statements like that in official reports; correct?
MR. SLATER: Objection. You could answer.
A Sure, sure. And the crucial point is this paper did show up to 22,000 nanograms per pill. And that is about the equivalent of what you find in a package of cigarettes. So I mean it's not -- it may be that I could have written that sentence better. There's a lot of sentences there. And possibly, I could have been -- possibly, it's in here, or possibly, I could have written it better. But the main point is, this is a massive amount of a carcinogen found in these pills.

Page 214

Q Right.
But the German Central Pharmacy, the German's FDA equivalent, unless you find it, and I'm getting you a chance to do that later, never said that a pill of Valsartan was equivalent to smoking a pack of cigarettes as far as we know?
MR. SLATER: Objection.
A They said it had up to 22,000 nanograms per pill which is equivalent to a package of cigarettes. Whether they made that specific, I thought they did. It's possible I made an error or wrote unclearly. But they did establish a level of NDMA in these pills which is equivalent to a package of cigarettes.
Q Right. But let me just get this straight so I understand what we could take from your report.
When you have a reference after a sentence and you say this paper, you're suggesting that the paper covers that point; right?

Page 215

A Yes.
Q And you're suggesting that what you put down in the official expert report is in here, in the paper; correct?
MR. SLATER: Objection. You can answer.
Q That's what you're suggesting about that reference; correct?
A Yeah. As I said, it's possible I made a mistake with the reference, or I wrote the sentence a little bit sloppily. It's possible. But the central point there, that, you know, this group found a massive amount of NDMA in Valsartan, an amount of which is equivalent to a package of cigarettes.
Q Now, do you know what other errors or mistakes in terms of references are in the report? Have you spotted any other ones since you gone back and read it a couple of more times?
MR. SLATER: Objection for multiple reasons including foundation and argumentative.
A Sure. The one we discussed yesterday.
Q The paper, just misciting the paper. But in terms of having a statement like this as attributed to a regulatory agency that isn't in the paper, you're not aware of any other off-the-cuff error; right?
MR. SLATER: Objection. You can answer the question.
A I am unaware of any other errors.
Q If you come across any, will you tell me?
A Sure.
Q I know you said at Columbia since you became associate professor, there was like a change in the curriculum vitae and the parameters of that, requirements. Do you remember that?
A I do.
Q Are there any parameters at Columbia about papers you write, papers you author, citations? Do they have any like specific rigor required for some of those things?

Page 216

Page 217

MR. SLATER: Objection.
Q Is there any board -- obviously, plagiarism would be a bad thing.
Is there any board that reviews papers that professors at Columbia write?
MR. SLATER: Objection. You could answer.
A Not to my knowledge.
Q There's no panel that has to review them since they're going out under your name which is under the auspices of Columbia?
MR. SLATER: Objection. You can answer.
A They're Peer Reviewed by the journals.
Q But the university doesn't -- the institution doesn't weigh in on that?
MR. SLATER: Objection. Asked and answered multiple times. You can answer again. It's counsel's time. If she wants to ask the same

Page 218

question over and over, she can.
A No.
Q You have another citation on page 3 of your report. And I'll make sure I have the right one. You cite to an article, I found the reference, I think it's 31. Which one is this one? Oh. 3. Reference 3 and page 3. Okay. So this is the agency EM.
A Okay.
Q Referral under Article 31 of directive -- you see the numbers there. This is another one that you cite to.
A Okay.
Q Do you understand this was written in 2019 after the recall of Valsartan?
A Yes.
Q And you're citing it in the same place for that same reference about NDMA and NDEA being volatile organic compounds on various other sources. It's in the same spot.
MS. COHEN: I'll make this No. 10.

Page 219

(The above-referred-to document was marked as Exhibit 10 for identification, as of this date.)
Q This is the European Medicines Agency. What do you know about this group?
A This group, to my understanding, is like an EU, an EU FDA equivalent.
Q And have you -- did you know anything about this group before this litigation, getting involved as an expert here?
A I may have heard of them. I wouldn't say I'm deeply familiar with them.
Q So let's look at this one. I think you said this earlier, that NDMA can be created within the body; correct?
A Yes.
Q Which means it's an endogenous source of NDMA; correct?
A There is endogenous creation

Page 220

of NDMA, yes.
Q And let's turn to page 16 of this paper. We'll go to the paragraph that starts with -- and, again, did you read everything in these articles that you cited to?
A I read -- depends on the article. I couldn't say I read every word of every article I read.
Q It's not going to be a memory test. I promise.
A I read the substance of every article. And some of them in tremendous detail; some of them were a little bit less detailed.
Q Was this one that you were focused on?
A I read this one with some good attention to detail, yeah.
Q Because it was an agency?
MR. SLATER: Objection.
Q Do you tend to give those more weight?
MR. SLATER: Objection. You can answer.

Page 221

A Well, I looked at everything. I put everything together, the studies, the agencies, everything. This one is quite germane to the topic. I did read it in detail.
Q So on page 16, it says, "As happening in a real life context, intake of NDMA and NDEA --
MR. SLATER: I'm sorry. Where are you? I'm just trying to find where you're reading.
MS. COHEN: Page 16.
MR. SLATER: I know the page. I don't know where you're reading.
MS. COHEN: Second full paragraph, starting at the first of that.
Q "As happening in real life context, intake of NDMA and NDEA should be seen in relation to the overall intake of carcinogens, e.g., as benozo[a]pyrene and other PAHs -- I'm probably saying that wrong -- and also other nitrosamines that are present in common food sources

Page 222

such as grilled meat. Exogenous intake of NDMA and NDEA is however considered to be lower than intake of some other carcinogens."

Did I capture that right?

A You read it correctly.

Q And then it says, "The amount of NDMA and NDEA coming from endogenous sources through conversion of amines to NDMA and NDEA in gastric and other acid tissue environments is described to be higher than general exogenous exposure."

Let me tell you what my interpretation of that is. You tell me if I'm wrong or right.

That means the body is producing a significant amount of NDMA on its own; right?

A So it's a very interesting and somewhat controversial area. The first thing to establish there is that any study that has looked at endogenous production of NDMA is doing it by modeling and by inference. There's not

Page 223

really any way to study, to measure that. You'd have to, I don't know, vaporize a human and perform a chromatography on them. So there's no measurement. It's all by inference. And there are some studies, I think some of the ones that are referred to here, are also referred to by Hrudey, et al. that do point to very high levels of endogenous and NDMA production.

On the other hand, there are some like Choi, which I believe I've referenced in my report, which show a much less, a much lower level of endogenous production. So I don't think that we really know precisely how much NDMA is made within the body endogenously.

And the other thing is that it's highly dependent on a lot of other factors, such as what are you eating, like why are nitrites carcinogenic. Nitrites are considered carcinogenic because they're converted to NDMA when eating proteins in the acidic environment

Page 224

of the stomach. It's hard to point to a baseline of endogenous NDMA production.

Q You agree with this paper that you cite to and rely upon in your report that, again, the body's producing a significant amount of NDMA -- correct? -- endogenously?

A Yes.

Q You did not sort of factor that into your analysis of looking at the big question that started off your report? You didn't try to do any determination as to what impact that had; correct?

MR. SLATER: Objection. You can answer the question.

Q Did you come up with any measurements?

MR. SLATER: Objection. So which question is it?

A I'm sorry. I was thinking about the first question.

Q It was a recap of that one.

MR. SLATER: Objection. Lack of foundation.

Page 225

Q If you're not comfortable answering this, let me know.

MR. SLATER: Objection. I'm asking counsel, what is this? We don't know which question you're referring to.

Q Are you uncomfortable answering this? If you're not capable of this answering this, just let me know.

MR. SLATER: Objection. Argumentative. Harassing.

A Okay. So the question is, did I consider endogenous NDMA?

Q Yes.

A I certainly did.

Q Did you come up with any measurements, was my next question?

A A measurement of endogenous NDMA formation?

Q Yes.

A Yes. As I said, I saw numerous sources. They ranged widely on how much there is. So, you know, when you look at dietary studies, presumably, those people are all making endogenous

Page 226

NDMA. So if the studies still show a signal, that the exogenous NDMA is potent with respect to cancer, which many of them, though not all, many of them do, then you would assume that the correction for endogenous NDMA had been made, particularly since some of them explicitly studied nitrite consumption, protein consumption, et cetera.

Q And on page 3, again, further down in the next sentence, you say, "NDMA can also be created within the body," kind of making that same point that's in the article; right?

A Yes.

Q And you're talking about what circumstances after ingestion of nitrates and nitrates plus proteins are the point that we're making here; correct?

A Nitrites.

Q Do you know how to correlate or compare the level of NDMA in a Valsartan tablet versus the amount that's being made endogenously?

Page 227

MR. SLATER: Objection. You can answer.

A In my opinion, having looked at the literature on endogenous formation, I don't think that there is a solid evidentiary basis to make that comparison. As I said, I saw widely varying models as to how much endogenous NDMA is produced.

And furthermore, there is no direct study. There is no measurement of it. There's only a model of inference. And they vary greatly.

Q Do you know the amount of endogenous -- or do you have an opinion whether the amount of endogenously produced NDMA is more or less than the FDA's stated acceptable intake levels of 96 ngs per day in the Valsartan 320-milligram tablets?

MR. SLATER: Objection to the question. You can answer.

A I think almost all sources certainly think it's more than 96 nanograms per day. I haven't seen any

Page 228

studies that say endogenous production is less than 96 nanograms per day. But those numbers do vary quite a bit as to how much the endogenous production is.

And, you know, NDMA is carcinogenic and probably on a dose response curve. So more of it is bad. So if I already have X amount that I'm making and then I start taking Y amount, Y has hurt me.

Q You have no reason to believe that the NDMA, which is produced endogenously, is any different or less toxic than the exposure to the exogenous sources of the NDMA; true?

MR. SLATER: Objection. You can answer.

A I don't think that that's really known at this point.

Q And you don't have an opinion about that, therefore; correct?

MR. SLATER: Objection. You can answer.

A I leave open the possibilities that it could be more or

Page 229

less toxic.

Q In other words, you do not have an expert opinion on that topic; correct?

MR. SLATER: Objection. You can answer.

A Just to clarify, the question is, on whether endogenous versus exogenous is more or less dangerous?

Q Yes.

A Well, not to a reasonable degree of scientific certainty.

Q Okay. Fair enough.

Let's look at the -- let's see. So the next exhibit will be --

MR. SLATER: What was the EMA document?

MS. COHEN: 10. We'll mark as 11 the original Jakszyn.

(The above-referred-to document was marked as Exhibit 11 for identification, as of this date.)

Q And I'll refer you to the cites. This is Footnote 36 in the report. And that's the one that was

Page 230

originally there which we got last night. And then page 16 is I think where it's cited. And it's not really an appropriate cite right there. Is that what you were telling me before?

MR. SLATER: Objection.

A Yes, correct. On 16, the reference should not go to this report. It belongs to the other Jakszyn paper.

Q And you already told me that it's still applicable to the report overall -- let's look at under the discussion part. And it says -- this is 1499. It's the page on Discussion.

"This is the first study reporting relationships between both endogenous and exogenous exposures to NOCs and GC risk. The exposure of NDMA from food was less than 1 per day, whereas that from ENOC was 93 per day (Table 1)."

And then it says, "We found that non-cardia GC was positively associated with ENOC exposure but not with dietary NDMA."

Page 231

Do you see that?

A I do.

Q And then if you turn to Table 1, which shows that the mean daily exposure to endogenously produced N-nitroso compounds to be 93, is that MG?

A Microgram.

Q Per day. Thank you.

Can you convert what 93.05 microgram per day is in terms of ng per day?

A Sure. 93,000.

Q And, of course, 93.05 would be 93,050 to be exact; right?

A Yes.

Q Did you know -- and, again, there's been some reports on this -- that the endogenous production of NDMA estimated to result in exposures that are approximately 1,875 higher than the highest estimated levels of exogenous exposure due to the preformed NDMA in the food, drinking water and such? Do you read that?

A Well, as I said, I looked at

Page 232

multiple studies with respect to endogenous formation of NDMA. And the results varied greatly. There are studies I believe that are in Hrudey or referenced at least in Hrudey which come up with numbers like the one you just said. There are others like Choi, which are more on the order -- it's about 1,000, 1,300 nanograms per day.

But irrespective of what the baseline is, we still have the dietary studies, which fully weighted, you know, looking at them in their totality show an effect for doses of NDMA, you know, really getting into a little over 100 nanograms per day.

Q But you've seen this article; you read that part of it --right?-- when you read it or maybe not?

A Yes.

Q Again, you cited to it originally?

A Yes.

Q And you knew from this that

Page 233

there were studies -- this says this is the first study reporting relationships that show that the endogenous biochemical processes are far greater in terms of contribution to genome mutation than exogenous. You came across this and in other studies like this; right?

MR. SLATER: Objection. You could answer.

A Yeah. As I said, there are studies that show a lot of endogenous formation. There are studies that show much less. And these are all estimates. These are models.

Q You were not given the report -- we may mark it at some point -- the report of Lewis Chodosh, M.D., Ph.D.?

A No.

Q Have you heard of him?

A No.

Q Do you know who he is in this case?

A I think you mentioned him as a defense expert earlier.

Q Cancer biologist.

Page 234

A Okay.
Q That's not your area of expertise; correct?
MR. SLATER: Objection. You can answer.
A I mean I think I said multiple times, I am an expert on cancer. I am not a practicing cancer biologist.
Q You're not trained as a cancer biologist, are you, Doctor?
MR. SLATER: Objection. You can answer.
A I have extensive training in cancer biology.
Q You didn't take any schooling or extra training on cancer biology, did you?
MR. SLATER: Objection. You could answer.
A It was certainly covered in medical school.
Q Putting aside medical school --
A Putting aside my graduate school? Okay.

Page 235

Q Well, people learn about pathology in medical school, don't they?
A Yeah.
Q Maybe a pathologist does it?
MR. SLATER: No, counsel. Are you arguing with the witness or do you have a question for him?
MS. COHEN: No. I'm asking him.
Q People who go to medical school want to learn about pathology; right?
A Yes.
Q Doesn't make them a pathologist?
A Doesn't make them a practicing pathologist. I would hope they have some knowledge of pathology.
Q And cancer biology, that requires extra schooling and education. Have you had any of that?
MR. SLATER: Objection. You can answer.
A I've had a lot of education on cancer biology. I read articles.

Page 236

I've written articles related to cancer biology. I am not a cancer biologist in the sense of, you know, maintaining a research laboratory devoted strictly to cancer biology research.
Q But you haven't had any training beyond medical school and cancer biology. I'm not talking about reading. Do you have any advanced degrees?
MR. SLATER: Objection. You can answer.
A Advanced degrees other than my M.D.?
Q Yes.
A I do not.
Q Any specific courses or training in cancer biology, beyond your M.D?
MR. SLATER: Objection. You can answer.
A During my training, topic of cancer biology came up frequently. And I was educated on it, probably nearly a daily basis.

Page 237

Q Did you do a fellowship related to cancer biology?
MR. SLATER: Objection. You could answer.
A My fellowship did encompass parts of cancer biology.
Q What fellowship did you do?
A GI liver pathology.
Q Did you do any residency that covered cancer biology?
A Anatomic pathology residency certainly covers the biology of cancer.
Q Do you have any extra certifications as a cancer biologist?
A No.
Q Did you look at Dr. Chodosh's CV?
A No.
Q And let's look at page -- and, again, you've never held yourself out publicly, either through your expert witness groups, on your Columbia Web site, on your CV as being a cancer biologist; true?
MR. SLATER: Objection. You

Page 238

could answer.
A I think you're using the words "cancer biologist" as if it's some set-in-stone thing that to be a cancer biologist, you are -- you know, this is exactly what describes a cancer biologist. I certainly have deep knowledge about cancer biology.
Q Did you ever win any awards or honors in cancer biology?
MR. SLATER: Objection. You can answer.
A No.
Q Still in your report, let's look at page 3. And another reference I want to look at, I think it's the next sentence.
"NDMA (and related compounds such as NDEA) have been studied extensively in animal models, where it has been shown to be a potent carcinogen."
Is that your sentence there?
A Yes.
Q And you cite to No. 5 for

Page 239

that. That is the IARC monograph, I believe. 2020. And let's make sure I have that right.
So on page 34 of your report No. 5 is the IARC: Carcinogenicity, and the Lancet, 2020, just to make sure we're all on the same page as we go through this.
I take it you have not read this article before, getting involved in this litigation as a litigation expert; correct?
A Correct.
(The above-referred-to document was marked as Exhibit 12 for identification, as of this date.)
Q I'm going to hand you Exhibit 12.
And this is one of the things that you referred us to earlier today; right?
MR. SLATER: Objection. You can answer the question.
A Sure. This is not the main IARC document on NDMA.

Page 240

Q It's one of them?
MR. SLATER: Objection. You can answer.
A Sure. Well, the main one is a monograph. It's about 350 pages.
Q The good news is we'll probably get to that one.
A Okay.
Q So hang tight.
You've read this one.
Obviously, you cited to it; right?
A Yes.
Q So I have a couple of things to point out on this.
This is, I guess -- Lancet is a very well-known journal, of course; right?
A Yes.
Q One that's respected?
A Yes.
Q And this article, what it says, let's look at page 1 over on the right-hand column.
And it says, "The evidence

Page 241

in humans was inadequate as aniline's effects could not be differentiated from those of other bladder carcinogens in the most informative studies."
You see that?
A Yeah. I'm sorry to do this. This is a little embarrassing. But I have to admit it, this is the wrong cite. It's the wrong IARC cite. I meant to say the main IARC monograph. So 19 was what that should be cited to.
Q So you want to cite to 19?
A Yes.
Q Which is on page 34?
A Yes.
Q Which I think we'll probably get to in any event.
A This is not nitrosamine-related. I don't think I should have included this. I think every reference -- every cite to this should really be to 19.
Q Well, first of all --
A These are aromatic amines. It's not the same thing.

Page 242

Q But they're related?
A You know, they're chemically related, but they're not the same.
Q You understand why I'm going through this? You cite to this.
A It was a mistake on my part.
MR. SLATER: There's nothing for you to add. She's telling you something.
Q On page 2, let's go to the other cite I want to go to. It says -- let's see.
Again, on the left-hand column, it says, "The evidence in humans was inadequate, consisting solely of a bladder cancer case series with concomitant exposure to other bladder carcinogens."
That's what this article says; right?
A Yeah, but not talking about nitrosamines.
Q Well, it's talking about nitro -- what's the word? -- anisoles?
A Yeah.

Page 243

Q And then on page 2, let's go to the last sentence of this. This article that you cited to, it says, "The evidence for cancer in humans was inadequate as no data were available"; correct?
A Again, not related to NDMA, but, yes, that's what it says.
Q And it also says -- it says, "A working group of 19 scientists were involved here and that the assessments will be published in Volume 127 of the monographs" in the top part.
A Okay.
Q So further down, let's see, on page 3, I'm going to go back to your report. And I'll put aside your Reference 5.
And you also mentioned the World Health Organization earlier today and, of course, the IARC which is an arm of the World Health Organization you're talking about here on page 3. Do you see that?
A Yes.

Page 244

Q And do you agree that it's classified as 2A as you note there?
A Yes.
Q And this is also, I believe, Reference 6 which we see on page 3 on the bottom there. Let's pull out this IARC.
Is this the one you wanted to look at, this IARC?
MR. SLATER: This one?
Objection.
MS. COHEN: That's what he said.
Q Is this the IARC that you wanted to cite to?
A Let's cite to 19, 19 IARC.
Q We'll go through this one first. This is the one.
6 is listed in your report; right?
A Yes. That might be right. There's similar information involved.
Q And here is the IARC monograph, Exhibit 13.
(The above-referred-to document was marked as Exhibit 13 for

Page 245

identification, as of this date.)
Q This is your Reference 6; correct?
A Yes.
Q And 2A, do you agree, is defined as IARC states that Class 2A is appropriate classification for a potential carcinogen when there is limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals?
A Are you reading that directly from IARC?
Q Yes.
A I'd just like to see it.
Q You got it. I understand. I had flagged it last night. This is in your Reference 6, page 30. Just tell me when you're there, sir.
A Okay.
Q And, again, this is -- if we look back in your report, you say -- classifies NDMA as Class 2A. Reference 6 is what we're looking at. And then we look at page 30 to see what 2A says, not

Page 246

just the highlight and not just the header. It says, "This category is used when there's limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals. In some cases an agent may be classified in this category where there's inadequate evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals and strong evidence that the carcinogenesis is mediated by a mechanism that also operates in humans."

And it goes on to say, "Exceptionally, an agent may be classified in this category solely on the basis of limited evidence of carcinogenicity in humans."

And you understood that; right?

A Yes.

Q And that's what you meant when you said 2A in here; right?

A Yes.

Q Now, the part I'm curious

Page 247

on, page 3 in your report, if we go back to that, where it says, "In its monograph on processed meats, IARC refers to NDMA as 'genotoxic compounds.'" You have quotes there.

Is that in here, this article?

A Yes.

Q Can you tell us where it is?

A No. It would take -- I'd have to -- if we have an electronic version, we can probably search through it.

Q We can look, we being Bardia.

And did you read the entire document here? I know it's many pages.

A No.

Q On page 421 in this article, 421, about halfway down, I'll let you get there.

A Okay.

Q It says, "NDMA has been fed to mice, rats, hamsters, guinea-pigs, rabbits, dogs, pigs and monkeys. It

Page 248

induced tumors in all species when fed at doses of 1 to 13-milligram/kilogram bw per day for life"; correct?

A That is what it says.

Q And that concentration, if extrapolated to humans, would mean in a 50-kilogram, 110-pound human or adult getting from 50,000 micrograms to 650,000 micrograms per day in order to observe that effect?

A Sorry. What was that?

Q If you want to extrapolate that and figure out what is that concentration in humans, it would be in a 110-pound adult, 50,000 micrograms to 650,000 micrograms per day. You know that that's true?

MR. SLATER: Objection. You can answer.

A I don't know that to be true.

Q You haven't done that calculation?

A Correct.

Q Wouldn't that have been

Page 249

important in this article that you're citing to in terms of IARCs that you've cited to multiple times in your report to know how you could extrapolate to humans, what we're talking about?

A Well, there are several problems with that. First is, you can't just -- humans are -- there are differences between humans and animals. So there are similarities, and there are differences. And doses might not be easily extrapolated from one to the other.

Secondly, I mean this is what you do if you're aggressively trying to give them cancer. So I mean no one is saying that the purpose of these medicines was to give people cancer, whereas the purpose of these experiments is to give the animals cancer.

So if you want to be absolutely sure that everybody who took it got cancer, maybe you would try to run that calculation and do it. But I don't think that's what anyone is attempting.

Page 250

Q So the next paragraph underneath that says, "NDMA has been administered orally to mice, rats, hamsters, guinea-pigs, rabbits and fish. All species were susceptible to increased tumor formation in doses of 0.4 to 4-milligram/kilogram bw per day. Tumors were the most prevalent."

Again, there, did you make any extrapolation in terms of what that would mean in humans?

A Well, the EMA and the FDA did. So I read that in their reports.

Q Did you figure out that this means 20,000 micrograms to 200,000 micrograms per day to get that exposure?

MR. SLATER: Objection. You can answer.

A Again, you can't just extrapolate so easily between animals and humans. The purpose of these experiments was to give these animals cancer. And, finally, the EMA and the FDA did do those calculations based on the TD50 in the animal studies. And that's how they came

Page 251

up with their -- with some of their estimates.

Q We're going to get to those too.

You would agree that those levels of NDMA and NDEA are hundreds of times higher than the exposure issued in the Valsartan products? Do you know that?

A I don't recall what levels it said.

MR. SLATER: Objection.

Q Well, I'll tell you what they are if you want to know.

There are 50,000 micrograms to 650,000 micrograms, 20,000 micrograms to 200,000 micrograms. Those would be hundreds of times higher; true?

A Those numbers for what they mean -- and I don't know what they mean exactly in this context -- are higher than what was actually found in the pills.

Q On page -- let's go to another point on page 4 of your report.

Page 252

Just tell me when you're there.

A Sure.

Q You could put that aside if it's uncomfortable on your lap there.

So page 4 -- and you cite to 7 here -- that is the ICH M7 which we'll get to in a minute. This talks about a cohort of concern which they define as high potency. Here, you're talking about ICH, high potency mutagenic compounds. Do you see that?

A I do, yes.

Q And you agree that not all the compounds and cohort of concern are shown to be carcinogenic to humans; correct?

MR. SLATER: Objection. You can answer.

A I don't have an opinion on that.

Q You're just not sure sitting here right now?

A Right.

Q And, for example, all nitrosamines are included in a cohort of

Page 253

concern, but you know that not all nitrosamines are carcinogenic? You know that; right?

A I know that some are more potent than others. I know that there are non-volatile ones. But probably, that's true.

Q You just don't know, sitting here; right?

A I think it's probably true.

Q You've been studying this literature in your report in this case, and it's the first time you're reading these materials; right?

MR. SLATER: Objection. You could answer.

A I mean most of them, I've read for the first time in conjunction with this case.

Q The IARC 2020 monograph, you never read that before this case, did you?

A No.

Q The IARC 2018 monograph, you never read that before this case, did

Page 254

you?
A Nope.
Q The IARC 2019, which I know you want to get to, you haven't read that, have you, before this?
MR. SLATER: Objection.
A No.
Q The ICH M7, you didn't read that before this case, did you?
A I did not.
Can we do a break?
Q Yes, absolutely.
THE VIDEOGRAPHER: We are now off the record. The time is 2:52 p.m. Eastern Time.
(A short recess was taken.)
THE VIDEOGRAPHER: We are back on the record. The time is 3:11 p.m. Eastern Time.
Q So we're back on. We're kind of moving through some of these references. Let's see where I left off.
This is the ICH M7 that we have on page 4 of your report.
A Yes.

Page 255

Q I may have already said this before. Reference 7. I'm giving you Exhibit 14.
(The above-referred-to document was marked as Exhibit 14 for identification, as of this date.)
Q You cite to this -- it's on the bottom of 3, top of 4. It says "International Counsel for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) includes nitrosamines in a cohort of concern -- that we talked about before -- which they define as high potency mutagenic compounds. A mutagenic compound is one which can cause mutations in DNA and can lead to cancer."
Those were your words; right?
A Correct.
Q You're not familiar with ICH, are you, in general?
A I am familiar with them.
Q Now you are?
A Correct.

Page 256

Q And you understand that ICH has brought together regulatory authorities, pharmaceutical industry authorities to discuss some of these scientific and technical issues, collaborative group?
MR. SLATER: Objection. You can answer.
A Yeah. Sounds about right.
Q And have you read this -- and I'll call it the M7, if that's okay with you -- in full?
A In considerable detail.
Q Now, what it says on page 6 is -- let's see -- it states that -- Class 2 impurities like nitrosamines are "known mutagens with unknown carcinogenic potential."
You see that?
A I do see that as a definition of a Class 2 compound.
Q And it actually says, again, they have unknown carcinogenic potential. And it goes on to say, "Bacterial mutagenicity, positive, no rodent

Page 257

carcinogenicity data."
MR. SLATER: What page are you on?
MS. COHEN: Page 6.
MR. SLATER: 6, okay.
MS. COHEN: Did I say that wrong?
MR. SLATER: No. I misheard you when you said the page number.
Q What you said in your report was "well-known carcinogens"; right? You see that on the top of page 4?
A Yes. I see that there.
Q But what this says is actually known mutagens or unknown carcinogenic potential; correct?
A Well, as I sit here right now, I don't recall if ICH called this Class 2 or Class 1.
Q We may put this to the side and come back to it.
A Okay.
Q So let's move to -- we'll put this aside -- Reference 11 which is on page 5 of your report.

Page 258

MR. SLATER: You said page 5 of his report?
MS. COHEN: Yes. Page 5 of his report. And it'll be Reference 11 which is the Thresher article.
Q Do you recall that one?
A Yes.
Q This relates to the NDEA. You say on the top of page 5, first full paragraph, you say, "NDEA also identified in Valsartan and according to researchers, using both bacterial and rodent experimental data, may be the most potent carcinogen of any known nitrosamine," citing to this Reference 11 which is the Thresher article. That is Exhibit 15.
(The above-referred-to document was marked as Exhibit 15 for identification, as of this date.)
Q Do you recall reading this article?
A Yes.
Q Page 3, bottom of the right-hand column, it talks about, "NDEA

Page 259

is the most potent nitrosamine for which carcinogenicity data is available" is what --
A I'm not finding that.
Q I'm sorry. It's right down here. Do you see that?
A Yes. I see it.
Q On the next page, page 4, it says under Discussion, talking about the study in the article, "This has shown that despite the majority of nitrosamines being carcinogenic, approximately 18 percent of the data set resolved as non-carcinogenic based on the expanded data."
Do you see that?
A Let me just read and familiarize myself. Okay. Yes. 82 percent of nitrosamines are carcinogenic.
Q Right.
And 18 percent of this article are not; correct?
A Yes.
Q Your reference to NDEA, it

Page 260

could be the most potent; is that what you said there?
A I believe that is consistent with what the article says. It goes against the idea that all nitrosamines would be carcinogenic.
MR. SLATER: Objection. You can answer.
A A, I did not make that statement. And B, I agree. This paper shows that 82 percent are, and 18 percent aren't.
Q And, again, other than looking at the materials that were provided to you in this case that we're going through, you've never undertaken any independent research of NDMA or NDEA; true?
MR. SLATER: Objection. You can answer.
A Outside of litigation work and what is represented here, I have not.
Q Much of the extensive studies on NDMA have focused on the animal studies. You agree with that;

Page 261

correct?
MR. SLATER: Objection. You can answer.
A Yes. When we're talking about a mutagenic compound, you cannot ethically give this to people, really to any extent. It would be unethical. And nobody would sign up for it.
Q I want to go to next, talk about some of the FDA information.
A Okay.
Q Because I think we talked about that a little bit before. Let's pick up on that now on what the FDA had to say.
And starting on page 4 of your report, I think it's in the first full paragraph, second paragraph of the page, we talked a little bit about this before. But I want to get to some of the cites. The FDA set the maximum daily exposure to NDMA. These are the numbers we went over before. And you have a number of references here that you cite to, 9 and 10. 10 is FDA.

Page 262

MR. SLATER: Go ahead. I'm sorry. I don't want to object. But --

MS. COHEN: I'm going too fast?

MR. SLATER: No. I thought you were reading one paragraph. And then you were citing references to a different one. I'm not trying to interrupt.

Q You cited to FDA references; correct?

A Yes.

Q Did all of the FDA references that you cite to come to you from Mr. Slater?

A No.

Q Did you pull some yourself from the FDA?

A I did.

Q And you would agree it's important to consider all the FDA had to say; correct?

A I read everything that the FDA said that I could find and took it in

Page 263

context of all the other information that I was finding.

Q Now, on page 4, you used the term "maximum daily exposure limit"; right?

A I did.

Q But the FDA words are really acceptable intake, aren't they?

A As I sit here right now, I don't quite recall. If you show me the verbiage, I'd be happy to look at it.

Q Let's go to the February 28th, 2019 FDA press release.

(The above-referred-to document was marked as Exhibit 16 for identification, as of this date.)

Q I'm going to give you Exhibit 16. And if you look to --

MR. SLATER: Is this the one that starts -- it says "FDA Warns Mylan for CGMP Deviations"?

MS. COHEN: No. About six pages in, the one that starts with February 28th, 2019.

A Okay. I'm on that one.

Page 264

Q And what it says here, if you look at the bottom of the page, it talks about, "The acceptable intake is a daily exposure to a compound such as NDMA, NDEA or MMBA that approximates a 1:100,000 cancer risk up to 70 years exposure."

Have you seen that before?

A I have.

Q Had you read this specific document before?

A I did.

Q And do you agree having seen this now that the 96 nanograms of NDMA is the daily acceptable intake for Valsartan 320-milligram tablet?

A I believe it's an interim limit, actually. I think the FDA's guidance is to get it down to non-detectable. But in the interim, they will allow up to 96 nanograms.

Q Well, what you said on page 4 of your report is the U.S. Food and Drug Administration, FDA, has set a maximum daily exposure limit to NDMA at

Page 265

96 nanograms per day or 0.3 ppm. Do you see that?

A I do.

Q You don't say interim, do you?

A Well, it says quite clearly here, interim.

Q In your report?

A No. The FDA does.

Q But your report doesn't call it an interim; you talk about maximum daily exposure limit, but really, it's -- the phrase is the acceptable -- the acceptable intake.

MR. SLATER: Objection. You could answer.

A Sure. Right above that, you see interim on that. So it's interim acceptable intake.

Q Which you don't have in your report?

A I could have used that phraseology.

Q And then this also says, as we talked about, the 1:100,000 cancer

Page 266

risk after 70 years exposure.
You've seen that before, that statement?
A I have.
Q You don't disagree with this assessment, do you?
MR. SLATER: Objection. You can answer.
A I agree that it's the FDA's estimate. Doesn't necessarily mean it's true. And for the 1:100,000 person, it really sucks. But I don't disagree specifically. I agree it's the best estimate.
Q Again, you're not a biostatistician; correct?
A I am not.
Q And let's go to the next FDA document. This would be 28.
(The above-referred-to document was marked as Exhibit 17 for identification, as of this date.)
Q So I take it you've seen this one at some point too, another FDA?
A Looks familiar.

Page 267

Q And the FDA gov site, as we say. And turn to page -- get past the pictures, maybe three, four pages in. And, again, this is what the FDA is putting out at the time of this article to the public to reassure, provide information, whatever you want to say.
And the fourth bullet here, it says, "Nitrosamine impurities may increase the risk of cancer if people are exposed to them above acceptable levels and over long periods of time, but a person taking a drug that contains nitrosamines at-or-below the acceptable daily intake limits every day for 70 years is not expected to have an increased risk of cancer."
You see that?
A I see that.
Q That's what the FDA told -- I think you cited to the FDA earlier. That's what the FDA was telling the public; correct?
A Yes.
Q And you don't disagree with

Page 268

that; you don't have any reason to disagree with those statistics; correct?
MR. SLATER: Objection. You can answer.
A I accept that that method that FDA used to come up with that method is probably close to accurate.
Q Then it says in the next bullet on the next page that "Patients taking prescription medications with potential nitrosamine impurities should not stop taking their medications. Patients should talk to their health care professionals about concerns and other treatment options."
I take it you read that?
A I do. I did.
Q You certainly agree with that; that's something that a patient should consult with their doctors about; right?
A I certainly agree that patients should talk to their doctors. I don't believe that they should continue taking their medications.

Page 269

Q But, again, you don't prescribe these medications; true?
A That's true.
Q Other types of doctors and other specialties do the prescribing; correct?
A Correct.
Q And that would be people like internal medicine doctors, hypertension experts, that sort of thing; correct?
A Yeah. Nephrologists.
Q And you would defer to those --
A Cardiologists.
Q -- doctors in terms of their assessment in valuation of a risk versus benefit; correct?
A Generally, yeah.
Q Turn to another article. This will be 18.
(The above-referred-to document was marked as Exhibit 18 for identification, as of this date.)
Q So this is another one that

Page 270

the FDA put out on April 14th, 2019 by Scott Gottlieb, who was the former commissioner of the FDA.

You've seen this one, I take it?

MR. SLATER: This is Exhibit 18; right?

MS. COHEN: Yes.

A I don't specifically recall reading this one.

Q It says that, few pages in -- if you could turn to the paragraph starting with, "Patients should continue," it says, "Patients should continue taking their medicine until their pharmacist provides a replacement or their doctor provides an alternative treatment option even if they learn that their ARB medicine is recalled. The risk associated with abruptly discontinuing the use of these important medicines far outweighs the low risks that our scientists estimate to be associated with continuing medicine until the patient's doctor or pharmacist provides a safe

Page 271

replacement or a different treatment option."

And it says, "Despite these very low risks," the next paragraph.

Again, it's kind of more of the same from the FDA; correct?

A Well, I mean this, broadly speaking, patients who get anti-hypersensitive drugs are at an increased risk of a heart attack. So these people don't take Valsartan recreationally. They take it to prevent cardiac events. They certainly have every reason to expect and believe that their drugs will be free of contaminants. And this is a huge breach of their trust.

But whether they should stop abruptly, the FDA is saying not to stop abruptly but to go to your pharmacist and go to your doctor to get an alternative.

MS. COHEN: I'll move to strike that.

Q I appreciate your response.

Let me ask another question which is, you understand that the FDA had

Page 272

a comprehensive and constant working group, a multidisciplinary team of chemists, toxicologists, physicians, pharmacists, communication specialists, investigators, laboratory staff to address this issue?

A Yes.

Q And you didn't consult on this issue for the FDA, I take it; correct?

A Correct.

Q You certainly aren't positioned to disagree with the numerous FDA scientists on these issues -- correct? -- in terms of the risks being very low?

A Well, I mean I have done my own review of the medical scientific literature. And I don't think that the risk is that low. I think that we see particularly from the Al-Kindi article that even virtually no -- very little time for latency. There was really a rather significant increase in the risk of neoplasms associated with Valsartan.

Page 273

So I think that it will take time for all the studies to be conducted and for final answers to be known. But I don't think that risk is very low.

Q So you disagree with the FDA and the statement here and the scientists?

A Which statement?

Q This statement from 2019, which we've marked as Exhibit 18, you would disagree with the FDA and their scientists?

A With which?

Q That the risk is very low.

A Let's read the sentence where they say that. Then I can respond to you.

Q In the prior FDA cite, it says, "The risk associated with abruptly discontinuing the use of these important medicines far outweighs the low risk that our scientists estimate to be associated with medication until the patient's doctor or pharmacist provides a safe replacement or a different treatment

Page 274

option."
That's one.
A Okay. Well, there, what they're saying is they're talking about a period of a couple of days. They're talking about until the medication can be replaced with a clean one. So, yeah, you know, I don't necessarily agree or disagree that three extra days of Valsartan is -- I think actually, it does confirm some significant risk. I mean I wouldn't take three of those pills right now. But if I was at high risk of having a heart attack or if I stopped abruptly, I would be forced to take them.
Q Where does it say three days?
A Well, it says until the patient's doctor or pharmacist provides a safe replacement. So I mean I would assume that people would be going about that expeditiously, rather than taking contaminated medicines.
Q Yes.
You interjected three. I

Page 275

just want to make it clear. Three was your add; right?
A Yes.
Q And if we go back to the prior article in the FDA because that had other information, I think it was 17, you asked whether you disagreed with the FDA and the scientists on this, and the fourth bullet on the page, we talked about where it says, "Nitrosamine impurities may increase the risk of cancer if people are exposed to them above acceptable levels and over long period of times, but a person taking a drug that contains nitrosamines at or below the acceptable daily intake limits every day for 70 years is not expected to have an increased risk of cancer."
Are you going to disagree with that statement?
A No. I think I've already said I don't have any real basis to disagree with that statement. But the contaminated Valsartan didn't have less than 96 nanograms per pill. I mean we're

Page 276

talking about 20,000, even up to 76,000. And that's only of what was tested. So these people were taking wildly above the acceptable levels, perhaps more than any people have ever taken before and over certain periods of years.
Q But, again, you are not disagreeing with that statement I described; correct?
A That statement pertains to acceptable levels, which are under 96 nanograms, which I don't specifically disagree with.
Q You don't disagree with the Bullet Point No. 4 that I just read to you there; correct?
MR. SLATER: Objection. You can answer.
A I think I've just answered it.
Q Well, I just want to be clear because at the end, I want to make sure -- you don't disagree with this Bullet Point 4; correct?
A I don't disagree with that.

Page 277

Q I have one other --
MR. SLATER: Last question.
MS. COHEN: Oh, stop.
MR. SLATER: She's like one other question.
Q So, again, Doctor, why don't we pull this out. This is Dr. Chodosh's reports since we talked about it. And I want to make sure you can look at it if you want to. It cites to a reference, but it was in book form. So I didn't have enough time to get it. So that's why I'll just mark it and let you look at it.
MS. COHEN: We'll give you a copy, Adam, if you want.
MR. SLATER: Yes. I'm just seeing. I thought I might have it here.
MS. COHEN: We got it for you.
MR. SLATER: I didn't bring it.
MS. COHEN: We'll mark this as Exhibit 19.

Page 278

(The above-referred-to document was marked as Exhibit 19 for identification, as of this date.)
Q I know you haven't seen the report. And, again, the reason I'm not showing you this cite is not because I'm holding it back, but because it was in book form. And we don't have it yet.
The page 124 -- I'm sorry. Page 30, paragraph 124, are you there?
A Yes.
MR. SLATER: I'm sorry, Lori. You said page 30?
MS. COHEN: Page 30, Cite 124.
Q So it talks about the American Conference of Governmental Industrial Hygienists.
Have you read that?
A No.
Q You haven't seen that, I take it?
A Never heard of that.
Q And it says, "Has classified carcinogenicity of NDMA as Group A3 which

Page 279

denotes a confirmed animal carcinogen with unknown relevance to humans."
Have you heard that classification?
A Nope.
Q It says, "Specifically, the A3 designation indicates that 'the agent is carcinogenic in experimental animals at a relativity high dose, by route(s) of administration, at site(s), or histologic type(s), or by mechanism(s), that may not be relevant to worker exposure. Available epidemiologic studies do not confirm an increased risk of cancer in exposed humans."
Not aware of that study?
MR. SLATER: Study?
Q Of that?
A It's basically impossible for me to react to this without knowing more about, A, this group of people, and, B, when they published what they published. It seems like they're looking at worker exposure. I don't know if this came out before the Hidajat study which

Page 280

did show people who were exposed to NDMA through the workplace.
Q What was the date on that one?
A I don't know.
MR. SLATER: It's referenced 38.
A 2019.
Q Yes. This is 2019 too.
A Probably didn't have it.
Q But fair enough. I don't have it with me.
So I just want to see if you've seen it, and the answer's no?
A Yes.
(The above-referred-to document was marked as Exhibit 20 for identification, as of this date.)
Q Exhibit 20, this is February 2021 guidelines that came out by the FDA. I don't think you cited for that.
Have you seen this one?
A Yeah, I did. I have seen this. I think it's one of my supplemental reliances.

Page 281

Q We'll obviously check. But the reason I want to bring this up is I think you said earlier that the 96 nanograms were interim levels?
A Yes.
Q And here we have on page 10, this has a section called, A, Acceptable Intake Limits. It says, "The FDA recommends the following several intake (AI) 31 limits for nitrosamine impurities."
So this is moved from interim to being part of this guidance document; correct?
MR. SLATER: Objection. Lack of foundation.
Q If you know.
A I need a minute to re-review it.
MR. SLATER: I can just tell you -- do you want to know why I'm objecting? I don't know if this is only geared to Valsartan. So I just want to make sure that the question doesn't suggest that. I'm not saying

Page 282

it does or it doesn't. But if it does, I'm just preserving my objection.
A Okay. It looks like they left the word "interim" out of this.
Q On one of the supplemental lists, you did cite to this one; right?
A Yeah. I've looked at this before. I'm pretty sure.
Q It's on the first supplemental list we got from Mr. Geddis 48 hours ago or thereabouts. So we've confirmed that. You could put that aside.
A Okay.
Q Keep things moving.
Now, this quote that you have on page 4 of your report, the old adage, "the dose makes the poison," is that a phrase you've used before?
A Sure.
Q It's not new to this report?
A New to me?
Q Yes.
A No. I'm familiar with this

Page 283

phrase.
Q But have you ever said it before?
A Probably. I don't specifically recall saying it.
Q Have you ever written it before?
A Not that I recall.
Q Do you know whether it's dated or cited in any other expert report?
A It's sort of a cliche in medicine. It certainly could be in many reports. I don't know.
Q I think I know the answer to this. I just wanted to make sure.
You cite to in your report I think three different employees of Teva, my client in this case. And you're obviously not giving any opinions about sort of how the company did things. That's outside of your purview for purposes of this deposition; correct?
MR. SLATER: You're talking about like how the nitrosamines

Page 284

occurred, the testing and all that?
MS. COHEN: Right.
Q That's not -- even though you referenced reading the reports, that was just for specific kind of markers or information?
MR. SLATER: Objection. You can answer.
Q Again, you cited to depositions, but you're not here to give any comments about on how the company handled things?
MR. SLATER: He's not giving any liability opinions against Teva at this stage of the litigation or against any manufacturers at this stage. I think we agreed to that.
Q You were citing to them, but not getting into the details of that?
A Whatever statements I made, whatever context I cited to is what I would say about it.
Q This is another press release.
(The above-referred-to

Page 285

document was marked as Exhibit 21 for identification, as of this date.)
Q I want to see if you've seen this one, Exhibit 21.
Have you seen this one before?
A Certainly.
Q This is the one that has -- I think this is part of your materials, the laboratory analysis chart?
A Yes.
Q Which I think you inserted in your report at some point?
A I'm sure I cited it. But I don't think I inserted it.
Q And the FDA in this press release, again looking at the estimated risk on page 1, this is their statement. "Laboratory Analysis of Valsartan Products" is what it says at the top. And this is where they talk about the LOD or limit of detection. We've seen that.
A Yup.
Q And it says in the next paragraph, "The FDA expects the actual

Page 286

cancer risk to most consumers to be lower than our estimate."

And you don't have any reason to disagree with that; correct?

MR. SLATER: Objection. You can answer.

A Let me just find the exact statement that you're referring to.

Q Sure. It's the third paragraph.

A Well, I don't know that I entirely agree with that statement.

Q You just don't know, one way or another?

A Well, FDA didn't disclose how they did their calculation. But EMA did a similar calculation. And they did disclose the methodology. And what they did is they extrapolated TD50, tumor dose 50, for animals based on the mean value of nitrosamines of NDMA that they found in their analysis.

So the mean, means that half the people have more -- or half the measurements are higher, and half the

Page 287

measurements are lower. So, you know, for any individual person, you don't have a 1 in 8,000 risk. The risk is going to be different for each person. This is maybe a big-picture calculation. But it's not applicable to an individual person.

Q What it says is the FDA estimates that if 8,000 people took the highest Valsartan dose, 320 milligrams containing NDMA from recall batches daily for four years, and maybe one additional case of cancer over the lifetime of the 8,000 patients?

A Right. That's an estimate. Since the numbers are fairly similar to EMA, I'm going to presume they probably used the same methodology which is based on the mean. And the mean, as I said, half the people had a higher dose than the mean.

Q So are you taking the position that you disagree with the FDA and what they say here about the cancer risk being lower than their estimate?

Page 288

MR. SLATER: Objection. You can answer.

A Look, the FDA is usually right. But they're not always right. No agency is always right. So I don't likely say or flippantly say I disagree. But I think that this is one of the instances in which they could be wrong. Based on the data that I see, particularly some of the already published data, I think that there are going to be more cancers than that.

Q Could be wrong, but you can't say that within a reasonable degree of medical certainty; true?

A Well, it's an estimate. So I'm opining basically about an opinion at this point.

Q You didn't do any study yourself; correct?

A No.

Q And you're referring to some of the --

A I assume you mean I didn't do a study where I personally calculated

Page 289

a dose response?

Q Yes.

A I did not do that.

Q You didn't take the data that the EMA and the FDA used and run any calculations yourself?

A Right. I didn't make my own model based on their data. But I did read the published literature, specifically with respect to cancer potency, including what we're already seeing in the use of Valsartan. And I drew a conclusion which I think this is going to be worse than what FDA states here.

Q And that's totally speculative on your part, isn't it, Doctor?

MR. SLATER: Objection. You can answer.

A Sure. Well, it's not speculative. I'm basing it on Peer Review published literature.

Q Which literature?

A Well, Al-Kindi showed an

Page 290

effect; Gomm showed liver cancer effect.
Q Any others?
A I believe it's Pottegård.
Q You cite to three in your report. You don't cite them necessarily by name. But you cite three articles on pages 25 --
A So Pottegård was showing -- didn't reach the statistical significance yet. But there are trends towards increased cancer, including 46 percent increased risk of colorectal cancer and 80 percent risk of uterine cancer.
Q Did not reach statistical significance; true?
A That is true. But those trends are very disturbing. And I think, you know, this is a very short latency period. So give this more time to develop. And these numbers could be -- well, let's say they can get a lot worse.
Q And it's funny. We're going to go through your part about latency periods with the Valsartan studies.
You say it's a very short

Page 291

latency period, you said?
A Yes. With respect to cancer, short latency.
Q You do say in your report, "Some common carcinogenic exposures can take decades, 30 years or more"; right?
A Some, yeah; some less.
Q That would not be short, would it?
A 30 years?
Q Yes.
A No.
Q We'll circle back to that in your bell curve discussion a little bit. I just want to finish this part.
A Sure.
Q Now, none of the cites of the literature that you established in your report establishes an increased risk of cancer from the oral ingestion of NDMA -- NDMA containing Valsartan products in terms of human carcinogenicity; true?
A False.
Q And, again, when you say

Page 292

"false," are you citing to Al-Kindi, Gomm and Pottegård or are you citing to the dietary studies?
A Well, I'm not -- I excluded my answer just now to not include dietary studies because you asked specifically about Valsartan. But the ones that show statistically significant potency for cancer from Valsartan itself are Al-Kindi and Gomm.
Q Now, you haven't seen -- because you've only been given Dr. Catenacci. You haven't seen what any of the defense experts -- and I'll tell you there are nine in total -- had to say about your report and your opinions and your assessment of the articles; correct?
A Correct.
Q You haven't seen any summaries of them from plaintiffs' counsel?
A No.
Q Has Mr. Slater or his team told you what they had to say about any of these articles in your use of them?

Page 293

A He mentioned a few particular points.
Q What points did he mention?
A It's hard for me to remember specifically what we discussed.
Q And I'll jump through some of this. So we may get it to anyway. I'm curious.
When Mr. Slater was talking to you in one of your recent meetings or discussions, did he say let me tell you what so-and-so has to say about you? They each had sections about you. Did he tell you that?
A He made a couple of comments about it. Again, I'm having a hard time recalling exactly what was said.
MR. SLATER: Just to be clear, we're going to be able to ask all your experts about all the discussions with counsel; right? It's open season; right? I didn't object. But I assume no defense lawyer is going to object when we question the defense experts about

Page 294

discussions with counsel.
MS. COHEN: I'm not agreeing to that.
MR. SLATER: Then I object. Move on to another subject.
Q I'm asking you, are you aware of what the defense experts have said about you?
MS. COHEN: That's fair.
MR. SLATER: It's a different question.
Q Are you aware of what they said about you?
A As a professional scenario, I hope they haven't said too much about me.
Q I'm sorry.
A As far as my report?
Q Yes.
MR. SLATER: They said some stuff about your musical taste.
A You know, as I said, Mr. Slater made a couple of comments about --
MR. SLATER: Don't talk about what I said.

Page 295

THE WITNESS: Okay.
MR. SLATER: They don't want to have an even playing field on that. So we're not going to go there.
A Nothing jumps out as a major thing.
Q You said Al-Kindi and Gomm are the ones you cited to?
MR. SLATER: Objection. I object to the characterization.
A Yes.
Q What's a scientific method?
A What is a scientific method?
Q Yes.
A Hypothesis-driven, evidence-based research, testing, testing replication.
Q Have you ever heard that the scientific method or heard or read scientific method is that the null hypothesis should be true, that there's no association of causation unless it's proven otherwise?
A That is a statement I've

Page 296

heard before.
Q In your report, you did the opposite; correct?
MR. SLATER: Objection. You can answer.
A Well, I mean in some situations, that statement that you made is a little bit misleading; you know, if I want to know if jumping out of the ninth floor is harmful, should I start with the null hypothesis or could I use a little bit of common sense?
Q Just to be clear, on page 11 -- I think we covered some of this before -- you actually do the opposite of the null hypothesis study?
MR. SLATER: Objection. You can answer.
A In the very specific case of someone being exposed to a significant amount of a carcinogenic compound and then developing a cancer, I would start with a very high index of suspicion that that carcinogenic compound contributed to their cancer.

Page 297

Q But that's understood.
But that's not what you did; you didn't start with a high degree of suspicion or whatever your quote was; you started that the assumption that exposure to a human carcinogen contributed to this carcinogenesis; you did the opposite of the null hypothesis? Wouldn't you agree with that?
MR. SLATER: Objection. You can answer.
A Again, in this specific context, I don't think that one needs to start with the null hypothesis by the same reasoning that, you know -- well, I gave an example.
Q Do you agree that what you did in your report with your assumptions as you noted, page 11 and into page 12, you did the opposite of a null hypothesis?
MR. SLATER: Objection. You can answer.
A I think it's unfair to characterize the whole report based on

Page 298

that statement.
Q I'm going to then -- I won't state the entire report. I'm going to say, you're dealing with the key question, the core question that we discussed earlier.
You did the opposite of a null hypothesis; true?
MR. SLATER: Objection. You can answer.
A No. I don't think the things that are dealt in this report really impact -- let me read the statement again, please.
Q Okay. Page 11.
A So in that statement, it's talking about any patient, talking about a particular patient. I'm not talking about a general approach or methodology to reviewing scientific literature. So, no, I wouldn't agree with your characterization.
Q The crucial part is it starts with the assumption that exposure to a human carcinogen contributed to

Page 299

carcinogenesis in the patient cancer unless there is convincing evidence to the contrary.
Is it your position that is not the opposite of the null hypothesis?
MR. SLATER: Objection. You can answer.
A Sure. That's dealing with looking at a particular patient. It's not dealing with taking the literature as a whole.
Q Does that say anything about a patient in there?
A Yes.
Q Any patient?
A That is the part about a patient and the previous sentence. Therefore, for any patient. Both make specific reference to specific patients.
Q Page 24 is where you get into the discussion of the Valsartan articles that we mentioned a little while ago. So just so you know where I'm going. And we'll pull them out here in just a few minutes.

Page 300

So, first of all, you talk about the three studies.
Again, you agree these are Gomm, Pottegård and Al-Kindi; right?
A Those are the three that are being referred here.
Q When you talk about the Danish study, that's Pottegård; is that right? German study's Gomm, and the study looking at adverse events reported to the FDA is Al-Kindi? I just want to make sure we're on the same page.
A The FDA one is certainly Al-Kindi, I believe it's true; Pottegård is Danish; and Gomm is German; Al-Kindi, American.
Q First of all, you say in the very beginning, you talk about the potential latency period is extremely short in each study.
A Yes.
Q And you talk about the latency period -- precise latency period is still being studied, and the maximum follow-up in the study is six years, a

Page 301

pretty short latency period in most cancers; right?
A Yes.
Q What you're saying there is that the studies are too short but the latency periods are long; right?
A You're asking me if I think biologically, the latency periods for cancer due to NDMA are long?
Q Yes.
A Well, as I say here, it's still being studied. So I think it's unclear at the moment.
Q So to be clear, to a reasonable degree of medical certainty, you cannot offer an opinion as to the latency periods involved in these cancers that are at issue in this case?
MR. SLATER: Objection. You can answer.
A There is some data to this effect. You could look at Hidajat which did have a latency period. I believe it was seven years, immediate latency period of seven years, Hidajat. So there is

Page 302

some evidentiary basis to offer an opinion in that regard.
Q I understand that.
And there are certainly experts who have offered opinions on that, the latency period.
I'm saying, you do not have an opinion as to a reasonable degree of medical certainty to the latency period because as you say here, it's still being studied; is that right?
MR. SLATER: Objection. You can answer again.
A It's still being studied. And we don't know exactly. But looking at the preliminary report, the first pieces of data, such as Hidajat, I think that was seven years, was a good study, big study.
Q You haven't offered any opinions specifically about the latency period; is that right?
A I haven't offered a specific opinion on latency.
Q Let's pull out Gomm.

Page 303

(The above-referred-to document was marked as Exhibit 22 for identification, as of this date.)
(The above-referred-to document was marked as Exhibit 23 for identification, as of this date.)
(The above-referred-to document was marked as Exhibit 24 for identification, as of this date.)
MS. COHEN: Why don't we pull out all of them: Pottegård, Gomm and Al-Kindi. 22 will be Gomm; 23 will be Pottegård; 24, Al-Kindi.
Q So let's look at Pottegård first.
A Okay.
Q And I notice when I asked you to tell me which articles quoted your opinion that there was some Valsartan studies that showed increased risk of cancer. You did not include Pottegård. You said Al-Kindi and Gomm. So I know this one is not part of that. But you do cite to it in your report. So I want to just cover it briefly; is that correct?

Page 304

A Well, when one is reviewing scientific or medical literature, different studies can get different weights for various reasons, quality, strength of association, many different factors come into it. Pottegård did not achieve, did not reach statistical significance which is why I can't put a lot of weight on it.
But there were trends towards increased cancer in Pottegård. So it is alarming. The other -- Pottegård has two really big problems. One is that they -- their study group was ZHP -- sorry -- ZHP Valsartan users. And their control group was users of other Valsartan products. So they don't say who their white list was.
And since this study was done, you know, we now know many different manufacturers had NDMA contaminated Valsartan. So it's quite possible that Valsartan use across the board, both in the patient and the subject's end controls, was artificially

Page 305

high because of Valsartan use; in fact, Al-Kindi supported that hypothesis.
Q Let me try to go through this quickly and just cover a couple of points.
One is, you agree that this did not show a statistically significant increase in cancer risk from NDMA contaminated Valsartan products; correct?
A Pottegård?
Q Yes.
A I agree.
Q And I think what it says here is on page -- three pages I think under results, I'll let you catch up there, it just says, "Overall, exposure to potentially (probably or possibly) NDMA contaminated Valsartan products showed no association with cancer compared with exposure to Valsartan products unlikely to be contaminated with NDMA and no evidence of a dose-response relation."
That's what you're pointing to; right?

Page 306

MR. SLATER: Objection. You can answer.
A Right. It says that. But they don't tell us which manufacturers were in which group.
Q But we agree that this could not be used to support the position that there's some increased risk; correct?
MR. SLATER: Objection.
A Yeah. I think that that would be overstating my position on that. I think, as I said, when you're reviewing medical and scientific literature, you can put various amounts of weight on various studies based on a number of factors. The fact that it didn't reach statistical significance certainly limits its utility. But it doesn't completely trivialize it.
As I said, there were trends towards increased cancer for colorectal and uterine cancer. And that in and of itself I think is quite interesting because those cancers are seen most commonly -- well, those are the most

Page 307

common cancers in people who have deficient DNA cleanup machinery.
Q So this cites to IARC for one. You see that in here?
A Pottegård?
Q Yes.
Pottegård cites IARC?
MR. SLATER: Where are you? What page? The first page right there?
MS. COHEN: No. It's a little bit further. It's the section on biological rationale. It's three from the back. These don't have page numbers.
MR. SLATER: I saw it on the front page.
MS. COHEN: Maybe it's on the front page too.
Q They're obviously referenced, the IARC; right?
A Yes. They're referenced, the IARC.
Q One of the things I think you criticized the study for was

Page 308

excluding individuals with Lynch Syndrome?
A Well, I criticized this article for excluding patients who had a previous diagnosis of cancer. And I mentioned that the cancers, which were showing trends towards increased incidents, are the cancers that are most commonly seen in patients with Lynch Syndrome. Lynch Syndrome was what I was just referring to when I said some patients have deficient machinery to clean up their DNA.
Q But you don't know of any studies that actually establish that NDMA or NDEA causes or accelerates cancer growth with Lynch Syndrome? You can't cite a study; right?
MR. SLATER: Objection. You can answer.
A Well, I know the mechanism by which NDMA -- NDMA causes mutation in cells. And it's precisely the kind of thing that you would want the enzymes of Lynch Syndrome to face. So I would say

Page 309

patients, if they have a deficiency in those cleanup -- in the cleanup machinery would be at very high risk from in-dose to digesting dosages of NDMA as described in Valsartan.
Q Is there any study that you can cite to for that? I know you said you know what kind of study there would be. Is there any kind of study we should be aware of?
MR. SLATER: Objection. You can answer.
A There's no study, yet, of Valsartan use in Lynch Syndrome patients in cancer outcomes.
Q So let's move to Gomm.
A Sure.
Q Which we marked.
That's one of the ones that you cite to as being supportive of your answer to the big question in the report about risk of cancer. This is one of the two; right?
A Well, I really -- so the big question was not answered on the basis of

Page 310

any two studies. The big question was answered on the basis of pretty much everything that I've referenced here. So the dietary studies, the animal studies, the WHO, the IARC. And these studies played a part, Gomm and Al-Kindi, as did everything else, including the negative studies.

Q In terms of actual studies, articles and studies for human carcinogen increase, the only two studies you cite here are Gomm and Al-Kindi; true?

MR. SLATER: Objection. You can answer.

A No. There are quite a few studies that I reference that show potency with respect to cancer for NDMA.

Q You're talking about dietary studies?

A Yes.

Q Putting those aside for this moment, these are the two studies: Gomm and Al-Kindi; true?

MR. SLATER: Objection. You could answer.

Page 311

A These are the two studies that specifically deal with the contaminated Valsartan pills and association with cancer.

Q And looking at this Gomm study, I know you've read it, of course; right?

A I've read it.

Q You probably read this multiple times since it's one of the two that you cite to for that particular issue?

MR. SLATER: Objection. Lack of foundation.

Q Did you read this recently?

A Relatively recently.

Q Last night?

A No.

Q Today?

A No.

Q Sometime in the last week?

A Maybe. One to two weeks.

Q Conclusion of the study -- I'm kind of a highlights person -- conclusion on page 1 is, "These findings suggest that the consumption of NDMA-contaminated Valsartan is associated with a slightly increased risk of hepatic cancer; no association was found with the risk of cancer overall."

Page 312

MR. SLATER: Objection.

A That's what it says.

MR. SLATER: Objection.

Q And you read the article, and you know that's not what it says, but that's what it found; right?

A In a short time frame, yeah. I think that studies like this in ten years might look dramatically different. But for now, they found already an increased incident of liver cancer which is a deadly and horrible disease and no other causative associations thus far.

Q Did you learn in your preparation today what other experts had to say about the Gomm article and the failings of it?

A No.

Q And I would say that what it says in the conclusion, which comes obviously at the end of this 35762, it says --

Page 313

MR. SLATER: You're talking about the conclusion?

MS. COHEN: Yes.

MR. SLATER: Let me just get there.

MS. COHEN: It's before 361.

MR. SLATER: Okay. I'm there.

Q It says, "We detected a small, yet statistically significant increase in the risk for liver cancer with the use of NDMA-contaminated Valsartan while no association was found for overall cancer risk or other examined single cancer outcomes" similar to what it says in the front part.

Then it says, "However, the present study can only state the existence of a statistical association. Causality cannot be inferred"; right?

MR. SLATER: Objection. You can answer.

Q That's what it said; right?

Page 314

A It did. And it goes on to say, "Long-term effects of regular use of potentially NDMA contaminated Valsartan for more than three years could not be evaluated because of the currently still relatively short follow-up time."
Q Let me ask you a few additional questions about Gomm.
A Sure.
Q While found a statistically significant association, there was no dose-dependent effect observed; correct?
A Is there a specific line, part that you're referring to where it says --
Q No. I'm just asking if you know that.
A I don't recall if they commented on that.
Q So this is 358.
A Okay.
Q And on the right-hand column about three quarters of the way down, it says, "However, no dose-dependent effect on the risk of liver cancer was found for

Page 315

higher exposure to potentially any NDMA-contaminated Valsartan."
Do you see that?
MR. SLATER: Sorry. What page did you say?
MS. COHEN: 358.
Q You see that?
A Okay. I see that.
Q And the study did not control for other risk factors for liver cancer.
Do you agree with that?
A Well, right above where you just highlighted, it says, "The association with liver cancer remains stable after basic adjustment for age and gender and also after additional adjustment for hepatitis and other liver diseases."
So I think that it did certainly make adjustments for hepatitis and liver diseases.
Q Also, this study did not correct for multiple testing, i.e., testing for an association for multiple

Page 316

types of cancer one type at a time? Are you aware of that?
A Where are you reading that?
Q From my expert's report. just being honest.
A Can you give it to me again?
Q If you don't know that, it's fine.
A We could move on. I didn't quite get the question. But we could move on, if you want, or we could go through it again.
Q No. I want to keep moving.
The last part was, it did not correct for multiple testing.
A Multiple testing.
Q Testing for an association for multiple types of cancer.
A I don't think I totally understand what the expert was saying with that comment.
Q I'm sure he can handle it far better than I can.
And, again, it ends with, "Causality cannot be inferred" in the

Page 317

conclusion part.
You saw that; right?
A Yeah.
Q Now, Al-Kindi is our last one that I want to go to. And we marked this. You should have it over there. Two pages in total; right?
A Yeah.
Q This is the one that the FDA -- adverse event reporting that you mentioned in your report?
A Yeah.
Q And this is the one -- tell me if I'm wrong about this -- that we talked about before where this came after the recall -- and I may get objected to -- but I think you said this had sort of the impact of the press and PR and the recall leading to kind of a spike; is this what you were talking about?
A Yeah. So I think what this article was really kind of saying -- and I'm going to make the case of it very believed, actually -- but what they were saying is, wow, if you look at the chart

Page 318

on page 2, they're saying, oh my God, look at how many tumors were reported as adverse events after the recall. And so, you know, these people taking these medicines must have panicked. And anyone who got cancer blamed it on their drug. And, okay, fine, certainly, people who see this in the news and recently gotten a diagnosis of cancer may make that conclusion, not necessarily an error. They could be right. But what to me really jumped off the page, if you look on the first page of this, the fourth paragraph, reporting odds ratio for neoplasm adverse event, increased from 1.7, and then it gives paren 1.3 to 2.1, pre-recall to 7.1 post recall. So that's saying, wow, it went from 1.7 to 7.1. And that's a lot. But what that 1.7 is, is a pre-recall number showing the odds of reporting a tumor as an adverse event from Valsartan compared to other ARBs was 1.7, meaning 170 percent other ARBs or a 70 percent increase to other ARBs. So there's no psychological explanation for

Page 319

why that number should be 1.7 pre-recall.

And just to put a fine point on it, it indicates that Valsartan use was associated with tumor development or at least the reporting of tumors before the recall.

Q. So, first of all, you talk in your report on page 26 about this article, and you say a massive spike in neoplasms reported adverse events; right?

A. What page?

Q. Page 26 in your report.

A. Yes.

Q. Neoplasms are not cancer?

A. Many of them are. In old people, most of them are. But there are some that are not neoplasms. That's true.

Q. They're not all malignant?

A. Not everyone is malignant. But they're tumors. They are tumors. Not every neoplasm is a tumor.

Q. What's particularly striking about the article was the calculated risk of reporting a neoplasm as an adverse

Page 320

event was 70 percent higher for Valsartan users, compared to consumers of other angiotensin receptor blockers, even before the NDMA contamination was announced.

Where in the study do you derive this statistic from?

A. Well, I just explained it. If you look at the fourth paragraph on page 1 of this study, reporting odds ratio for neoplasm AEs, adverse events, increased from 1.7. So 1.7 means that those users, users of Valsartan had a 70 percent higher risk of reporting a neoplasm adverse event pre-recall.

Q. Right.

But --

A. 1.7 is the statistic. Then it shows the range there, the confidence interval of 1.3 to 2.2.

Q. But you go from neoplasm to cancer; you're conflating those two words, aren't you?

A. Well, they're all tumors. And I'm sure most of them are cancerous

Page 321

because these are old people taking this drug.

Q. But you don't know that, do you? Do you know that all of those neoplasms are cancerous?

A. I didn't say all of them are cancerous. I said a lot of them are cancerous.

Q. You're speculating on that, aren't you?

MR. SLATER: Objection. You can answer.

Q. You said most of them are cancerous.

A. Most neoplasms in people of the age group taking Valsartan are cancerous. Some are benign tumors. I'm sure there are some benign tumors in there. But my statement is accurate.

Q. You don't think you're speculating when you say that?

A. I'm basing it on well-known epidemiology that most neoplasms in people in their 60s and 70s are going to be malignant.

Page 322

Q There's a section in your report, Ranitidine Studies, page 28. The Yoon study also found -- I could pull it out. I'm sure you read it recently; right? Yoon. It's the only one you cite to in the section.
A I don't think it's the only study that I cite to in the section. I mean I did read this study. If we're going to talk about it in detail, I would like to see it.
Q I'm just going to ask you one question right now.
Are you aware that study found no association between cancer and ingestion in nitrosamines?
A I'm aware that this study found no association between the nitrosamine levels in Ranitidine and cancer so far. Ranitidine levels are much lower than what's been reported for Valsartan. And, again, this suffers from the same problems as Gomm and Pottegård which is that it may need more time.
Q So no one should rely on

Page 323

them with any degree of certainty, is what you're saying?
MR. SLATER: Objection. You can answer.
A They're one piece of the puzzle. We had to go through all of the research to take the disparate data points and synthesize them into an opinion.
I think I might like another break soon.
Q Why don't we do it now.
THE VIDEOGRAPHER: We are off the record. The time is 4:35 p.m. Eastern Time.
(A short recess was taken.)
THE VIDEOGRAPHER: We are back on the record. The time is 4:57 p.m. Eastern Time.
Q So, Doctor, I'm going to just shift gears a little bit, move away from the literature and your report for a little while and ask you some general questions that I have.
A Sure.

Page 324

Q And then we'll get where we get to.
So can you name for us as many human carcinogens that you could name?
A Oh, boy. Okay. Cigarette smoke, smokeless tobacco.
MR. SLATER: While you're doing that, objection to the question. But you can continue to answer.
A Radiation, asbestos, nitrosamines, Human Papilloma Virus, Epstein Barr Virus, Human T-cell Lymphoma Virus, Clonorchis, Chinese Liver Fluke, Schistosoma, Reflux. Well, that's not -- that's not an exogenous one. Hepatitis B Virus, Hepatitis C Virus, alcohol, certain asbestiform minerals, such as tremolite. There are probably more. I can keep thinking about them, if you'd like.
Q I'm going to ask you a follow-up question.
A Okay.

Page 325

Q Do you consider there to be a universal carcinogen?
MR. SLATER: Objection. You can answer.
A What do you mean by that?
Q That each type of these potential carcinogen has the same reaction.
A You mean across species?
Q Well, and in people in terms of type of cancer they cause.
A Can you ask the question a little differently? It's a little hard for me to get.
Q Well, for the various cancers that you named before, what types of human cancers do they cause? Do they cause the same types or different ones?
A For the carcinogens that I mentioned before?
Q Yes.
A I mean they -- each can cause various types of cancer. And there's a concept perhaps that -- they each can cause various types of cancer.

Page 326

Well, some would only cause one type of cancer. Hepatitis B or Hepatitis C, for example, causes liver cancer.
Q On page 18 of your report -- I know I was getting away from your report -- I want to go back to this one point. You said on page 18 -- it says, "However, it's worth noting that once a carcinogen has entered the bloodstream, it's likely that it can cause cancers in nearly any organ."
What's the basis for saying that?
A The basis for saying that is that once a carcinogen is in the blood, it can be pumped to any part of the body. And so many of the carcinogens that we mentioned before are not bloodborne.
Q And you'd agree that the presence of a carcinogen, whether it's NDMA or something else, in the bloodstream by itself, that fact does not make NDMA carcinogenic? The fact that NDMA is in the bloodstream, that doesn't make it carcinogenic?

Page 327

A It's the DNA damage that makes it carcinogenic.
Q Well, it still has to be metabolized, doesn't it?
A Yes. And then it causes DNA damage.
Q On the universal carcinogen, are you asking me to re-ask the question?
A Yes.
Q Is there any carcinogen that equally can cause all types of cancer?
A That's a concept I haven't considered before. So there's a concept in medicine called the multi-specificity, which I think would apply to this discussion, whereas if we say something is specific, that seems to exclude other avenues.
But take, for example, like cigarette smoking, it is a multi-specific carcinogenic. It can cause lung cancer. Obviously, it can cause head and neck cancers. It can cause bladder cancer. So it's multi-specific. And there are a lot of multi-specific carcinogens,

Page 328

universal, meaning any single organ in any single person, something can cause cancer. A carcinogen can cause cancer. I can't think of an example right now. Ionizing radiation, maybe.
Q Back to page 18 of your report, you go on to say, "It will be difficult for one to scientifically exclude the potential for a bloodborne carcinogen to cause cancer in any organ to a reasonable degree of medical certainty."
Again, you have no cite there; correct?
A There's no cite, right.
Q And you have no cite to give us for that statement, do you?
MR. SLATER: Objection. You can answer.
A It's an opinion based on my knowledge of biology and pathobiology. Probably, it could have been said better by adding "without prospective data."
Q It's your opinion there's no prospective data to support that; is that

Page 329

right?
MR. SLATER: Objection. You can answer.
A That's not exactly what I'm saying, no. I'm saying that carcinogens that enter the bloodstream like NDMA and its metabolites could potentially cause any cancer. Now, it may be true that over time, we'll learn it's more likely to cause Cancer Y, X and Z than A, B, C. But that data doesn't exist yet.
Q And can you point to any studies cited in your report that is determined that the NDMA will reach the bloodstream after oral ingestion for up to 20 micrograms of NDMA?
A Yes.
Q Which ones?
A Well, of course, it's well-known. It's a scientific consensus that NDMA does get into the bloodstream. That is not a contentious issue. I'll try to find the specific reference now. As far as I'm aware, there's not a shred of scientific argument against that

Page 330

proposition.
Q Well, it doesn't mean it's carcinogenic just because it's in the bloodstream; right?
MR. SLATER: Objection. You can answer.
A Yeah. I mean there are two different questions. If you're asking, is NDMA -- does NDMA get into the bloodstream, I think it's completely uncontroversial. I can probably find it in the WHO article from 2002, a reference, if you need it. But it's well-known there's scientific consensus.
As to whether or not it's a carcinogen being in the blood does not in and of itself make it a carcinogen, if that was your question.
Q Yes. That's fair.
And you don't have any specific citation, as you said, for those two sentences or one sentence -- no -- two sentences on page 18?
A Those two bolded sentences?
Q Yes.

Page 331

A There's not a citation to that. Those are professional opinions based on my knowledge and experience.
Q And one thing I meant to ask about, in your report, you talk sort of at the end about injuries and harm and what people experience.
Again, you're not offering those opinions today at this point in this litigation because you're not getting into any case-specific issues or assessing people, what they've experienced; is that correct?
MR. SLATER: Objection. You can answer. Do you mean he's not offering an opinion on any specific patient at this time?
MS. COHEN: Yes.
A Yeah. I mean --
Q I'll start with that.
A Yeah. I mean as a human, I feel for all the people who took this drug.
MR. SLATER: Her question is, when you made that statement,

Page 332

were you referring to a specific plaintiff in this litigation or was it a general statement?
THE WITNESS: General statement.
Q And even on the general aspect of it, you haven't -- and, again, as you said, let me find the exact pages -- I don't want to forget to ask -- page 33.
You said, "Anyone who actually develops cancer as a result of being exposed to contaminated-Valsartan with NDMA and NDEA has been harmed."
This is a general statement you're making; if someone gets cancer, you consider that a harm; right?
MR. SLATER: Objection. You can answer.
MS. COHEN: I'm taking it one sentence at a time.
A Yes. Certainly, anyone who develops a cancer as a result of being exposed to contaminated Valsartan with nitrosamines has been harmed.

Page 333

Q But in terms of how they've been harmed, what long-term risks they have, what exactly they have suffered, again, that's not anything you're able to comment on today to a reasonable degree of medical certainty?
MR. SLATER: Objection. You can answer.
A I find the question a little bit overly broad. If, again, we're talking about any particular person, I'm not commenting today on any particular people with any particular disease.
Q Right.
And the next piece of it -- because I don't want to leave here and regret not asking this.
The next piece of it, even though you've given this general statement -- well, let me ask this.
You would offer the opinion that anybody who's developed cancer has suffered harm; right?
A That would again be overly broad. Anyone who develops cancer in

Page 334

what context?
Q In any capacity.
You obviously said you feel terrible for anyone who develops cancer; correct?
A I do.
Q And, again, it's a generalization that you feel like if somebody develops cancer from some exogenous source, they've been harmed; correct?
A Yeah. I mean the specific question you just asked, if people developed cancer from an exogenous source, then, yes, definitely.
Q But to go any further, in other words, in terms of what oncologic risk, what future harms someone might have, what they will experience, that again, you're not able to offer to a reasonable degree of medical certainty here because you haven't studied those issues?
MR. SLATER: Objection. You can answer.

Page 335

A Well, for some of these products, the degree of contamination is unprecedented in human history. As far as I know, there's never been a time where people might have consumed 50,000 nanograms per day of NDMA.
So, you know, for me to give an exact -- an exact risk rate, I don't think anyone can really do it right now. You could make models. You could make guesses. But we don't know the exact risk. And especially if you're going to talk about a particular person, then we have to look at the whole case.
Q You have not assessed, for example, the oncologic risk, the risk that they would at some point in their life develop cancer? You have not done a modeling or assessment of that; correct?
MR. SLATER: Objection. You can answer.
A I haven't done my own mathematical models. I have read through the studies, including the dietary studies, which do show -- both in many

Page 336

instances, they show a certain amount of NDMAs associated with a certain amount of increased cancer.
So I am directionally aware of what the risks may be. But for this particular question -- the Valsartan question is going to be different depending on which medications the patient was taking.
Q The amount of it?
A Yeah.
Q Time frame of it?
A All of that.
Q And confounding factors?
A All those factors come into play.
Q Multifactorial, it could be Valsartan, it could be combined with something else; so, in other words, sitting here today, whatever day it is today -- I don't even know -- 2021 -- what's the date today? Friday the 13th, you can't offer any opinion to a reasonable degree of medical certainty as to the risk of future harm or the

Page 337

increased risk? You haven't studied all that; correct?
MR. SLATER: Objection. You can answer.
A I don't agree with that characterization at all. I think -- so there's a degree of precision that I cannot provide because we basically don't have an evidentiary basis for what happens if you take multiple thousands of milligrams of this substance.
But I have looked at the evidence that exists. And that concludes dietary studies which show rather significant potency for NDMA causing cancer. So based on the dietary studies, as well as animal studies, if you're asking me if I can say to a reasonable degree of medical certainty whether these people have been harmed or not, I absolutely believe they've been harmed.
Q What you can't say to a reasonable degree of medical certainty is what the increased risk is they will at some point in their lives develop cancer?

Page 338

That's not something you can offer today; right?
MR. SLATER: Objection. You can answer.
A Like a precise percentage?
Q Yes, percentage anything, right.
A I could give -- it could be answered in a couple of ways. One way is we've never seen this much NDMA administered to people before. At the lower levels, I think that you could definitely make an analogy to the dietary studies.
Q So, again, I'll just go back to what I said before.
You haven't talked to any of these people; correct?
A If I can clarify my previous answer, you know, the dietary studies, some of them show about like a -- we can go to my report here. There are some that show 40, 60 or 100 percent increase risk for high dietary consumers of NDMA.
And so those dietary

Page 339

studies, the high consumers of NDMA are consistent with the very low end of the spectrum for contaminated-Valsartan pills. So I think in those instances, I could give you a relatively reasonable estimate of increased risk, the people who are taking 25,000 nanograms, 50,000 and 76,000 nanograms. I have no idea. No human has ever been subjected to that, to the best of my knowledge, but a lot.
Q Here's my issue.
Page 33, you throw in at the end this paragraph about harm, an unreasonable oncologic risk, having increased the risk; there's not a single citation there -- correct? -- in that paragraph.
A That's right.
Q You also do not express any opinion, other than these generalities, about the degree of risk, percentage of risk? There's no specificity here. You agree with that?
A No.
Q What do you mean no? Where

Page 340

is the specificity? Where are the percentages, the numbers?
A There's a difference between precision and specificity. I don't put any precise statements in here. But I do think the statements are specific to people -- I mean the statements read as it reads. But I don't consider them particularly non-specific. I mean they are sort of a closing statement.
But I think it's absolutely true that if you are a person in 2012, you had hypertension, you had X percent chance you were going to get cancer in your life. Me, everyone here has some percent chance they're going to get cancer. The people who took these medicines have a more likelihood of getting cancer.
Q But you cannot in any way give us a citation as to what the increase is; correct?
A I think I just explained that for people at the lower end of the spectrum, we can go to the dietary

Page 341

literature where the numbers are relatively analogous. And with that, we probably could put together a pretty reasonable model.
Q But you haven't done that here, have you?
MR. SLATER: Objection. You can answer.
Q Is there -- look at this paragraph. Is there any number in here? Is there any model in here? Anything?
MR. SLATER: You're talking about on this page?
MS. COHEN: Yes.
Q This is your chance to do it.
Is there any number here?
MR. SLATER: Objection. You can answer the question.
A I disagree that this is the place I would have to do that. I spoke in great detail in this report about the increased cancer rates for dietary studies. And we can look.
And for everyone where I had

Page 342

an amount of ingestion, I included that, that data. So we can look at the specific drug products and the specific levels of contamination. And then we can say, okay, if this is analogous to Study X and this is the increased amount of cancer for some of them as I said, I mean you could never ethically give someone tens of thousands of nanograms of NDMA.

Q Do you understand that if you didn't do some analysis or some calculation or some modeling put in your report, it's not in the report.

I'm asking you, did you do a modeling or calculation for harm or a reasonable oncologic risk anywhere?

MR. SLATER: Objection. You can answer.

Q Did you do it?

A I didn't do a calculation, no. I relied on calculations in the Peer Review literature.

Q In the dietary studies you mentioned?

A Yeah.

Page 343

Q And you didn't try to take those and extrapolate in this -- because this is the only paragraph where you talk about harm -- come up with any type of calculations for this litigation?

MR. SLATER: Objection. Mischaracterization of the report. You can answer again.

A So I didn't personally take any of the original data and model to do some sort of risk assessment model.

Q And none of the other experts who are part of the plaintiffs' expert team did so; correct?

MR. SLATER: Objection.

A I have no idea.

Q You haven't seen any of those?

A I have not seen any of them.

Q You haven't been told about any modeling they've done?

A No.

Q Or any increased risk analysis?

A No.

Page 344

Q Sitting here today, 2021, do we know all the reasons why people develop cancer?

A All the reasons, no. We know a lot of the reasons. But I couldn't say all.

Q Do individuals who are not exposed to environmental carcinogens develop cancer?

A Definitely.

Q Do individuals --

MR. SLATER: One second. Objection to the form. I just didn't want to step on your answer.

Q Do individuals who do have an inherent predisposition of cancer still develop cancer?

A Some, sure. Many.

Q Can observational epidemiologic studies prove causation?

Let me retract that and look at what you said on page 22. I'm going to withdraw that question for now.

Would you agree that DNA damage commonly occurs in the cells of

Page 345

our bodies as a result of endogenous processes or is it always external exogenous factors?

MR. SLATER: Objection. You can answer.

A It's both. Certainly both.

Q And you agree -- I think you said this earlier.

You agreed earlier that association does not mean causation? You agreed with that earlier?

A Right.

Q And you also agree that risk factors, not all risk factors are not causes?

A What's that?

Q All risk factors for cancer are not causes of cancer. Do you agree with that?

MR. SLATER: Objection. You can answer.

A All risk factors for cancer are not causes for cancer. As a general supposition, I would agree with that.

Q How long does it typically

Page 346

take to develop cancer starting from a normal cell without mutations until the time a cancer is clinically diagnosed or diagnoseable?

MR. SLATER: Objection. You can answer.

A Without knowing the specific cancers in question, it's almost impossible to answer that. There are some that can take ten years or more. There are some that can be detected on the order of weeks. So it's a really broad range.

Q There was one part of your report where you were talking about polyps. I'm trying to see where that is.

I'm going to ask you a question, how long does it take for a polyp in a colon to turn into invasive colon cancer?

MR. SLATER: Objection. You can answer.

A From the first day that it's a polyp to the day that it's a cancer, you know, there's not an exact timeline.

Page 347

But ten years or more in most cases with outliers.

Q So the latency period is long; correct?

A For colon?

Q Yes.

A Yes. But latency period is not a term I would use in that context.

Q What would you use?

A Just the rate of progression is slow until the point it's cancer, then it's fast, slowly, and then all at once.

Q If a polyp becomes an invasive cancer, can you tell what caused it to become invasive?

A Yeah. I mean this is -- that question gets at really the basis of colorectal carcinogenesis. And typically, when you have a polyp, you see the first mutation in a gene called APC, adenomatous polyposis coli, causes the polyp. As it progresses, the polyp requires additional genetic defects. So typically -- and, again, there are outliers. But typically, the next one,

Page 348

there's a mutation in the KRAS oncogene. At that point, it's still not usually invasive carcinoma. But the typical third hit would be a mutation in the TP53 tumor suppressor gene. And by the time that happens, there's a very good chance of the polyp becoming an invasive cancer. Often, you'll have a final hit, which is the TPC4 gene detected in pancreas cancer, although in this case, we're talking about it in relation to colorectal cancer. So the reason a polyp becomes an invasive cancer is because it requires additional somatic genetic mutation as I just described.

Q Is it your opinion to a reasonable degree of medical certainty that exposure to even a single molecule of a carcinogen can be sufficient to cause cancer?

A I would think that that's a very extreme statement.

Q So you would not express that opinion?

A As a general rule, that

Page 349

would not seem terribly plausible to me. There may be some substances that are so potently carcinogenic. I don't know what plutonium might do if put in the wrong place. But as a general rule, I find that statement to be -- I don't find that to be one molecule being terribly convincing.

Q As a general rule, you would agree, I'm sure, that common carcinogenic exposures could take decades to cause cancer; right?

MR. SLATER: Objection. You can answer.

A Sure. Some, definitely.

Q How many packs of cigarettes does it take to cause lung cancer in a cigarette smoker?

MR. SLATER: Objection. You can answer.

A A number.

Q What's the shortest period of time it takes to develop cancer, starting from the normal cell without mutations in key genes until the time a

Page 350

cancer is clinically diagnosed?
MR. SLATER: Objection. You can answer.
A I believe you asked that exact question. I'm virtually sure. The answer is the same. It doesn't matter. The answer is I can't answer that question without knowing the specific cancer in question. There are some that could take decades to become clinically apparent. And there are others that can become clinically apparent within a matter of weeks or even days in some instances. So it's an overly broad question. Weeks to decades, days to decades is my answer.
Q I take it that you do not have an opinion to a reasonable degree of medical certainty as to a typical period of time it takes for NDMA or NDEA to cause cancer?
MR. SLATER: Objection. You can answer.
Q Given the limitations of the studies we talked about earlier.

Page 351

A Well, the issue of latency -- and, you know, we got to that a little bit earlier. Maybe I didn't make myself entirely clear. We have some studies that get at latency, including Hidajat, which was I believe seven years, was the immediate latency period, which implies that for some, it's longer, ten years or more; some, it's less, three years, an order of three years.
And I think that Gomm, for example, has three years of follow-up. And it shows an increased risk of liver cancer. So the low end of the spectrum is probably a couple of years; the high end is still being defined.
Q While you mentioned the Hidajat, let's pull out that one which is I think cited on page 17.
(The above-referred-to document was marked as Exhibit 25 for identification, as of this date.)
(The above-referred-to document was marked as Exhibit 26 for identification, as of this date.)

Page 352

A Straif is the next paper referenced in my report.
Q Since you've referred to this Hidajat several times, this is the one about the lifetime exposure rubber dust fumes and nitrosamines and cancer mortality and a cohort of British rubber workers?
A That is the study, yes.
Q The study followed rubber factor workers; correct?
A It did.
Q And rubber workers were exposed to a variety of substances, including aromatic amines, which are known to be associated with an increased risk of bladder cancer?
A A number of substances, right.
Q This study did not take into account in any way, smoking or factor that in or out; correct?
MR. SLATER: Objection. You can answer.
A So what the study did that

Page 353

was very important, was they were able to estimate the exposures of the substances. So aromatic amines are one. NDMAs are another. So they did a careful analysis in that regard.
As to how they dealt with the issue of smoking, my guess is that a ton of people that worked in the British rubber industries, starting in 1967, smoked. But I don't have a recollection off the top of my head of how they dealt with that in this paper. I'm happy to take some time to go through it if you'd like.
Q You cited this in your report; correct?
MR. SLATER: Do you want him to find that and explain that to you?
MS. COHEN: No. I'm going to ask the question.
Q You cited this in your report --correct?-- this article?
A Yes.
Q On page 257, I think it's where the issue of smoking comes up. So

Page 354

on the bottom of this paragraph, you can certainly read through it, it ends with suggesting that confounding by a smoking cohort was likely not a significant confounding factor.
A I'm just reading through that section. Okay. I've read that section.
Q Does that answer the question about how they dealt with this cohort and the smoking aspect?
A Yes. They statistically modeled the potential for bias from smoking and concluded that it was not a significant confounding factor.
Q Now, this is the McElvenny. It's the next article that we gave you, No. 26.
You haven't read this one, have you?
A Did I cite this one?
Q No. I don't think so unless it came in one of the supplemental citations.
Have you seen this one

Page 355

anywhere?
A I'm not entirely sure if I did or did not. If I didn't supply it, I didn't rely on that.
Q So this is the same cohort as Hidajat from what I can tell.
A It may be or it may not be. Not having been really familiar with it, I can't agree to that.
MR. SLATER: Do you want to take your time and take a look at it since you've been asked the question?
THE WITNESS: Sure.
Q Let me ask the question.
You have never seen this before; right, Doctor? You've never read this?
MR. SLATER: Objection. Asked and answered. You can answer again.
A I don't have a specific recollection of doing so.
Q In terms of the study cohort, you can look at page 849, it talks about the assembly of the study

Page 356

cohort. It might help you get to the answer. And it even refers to the predecessor.
A So where is it that you're finding that this same cohort is the Hidajat cohort? I don't see that.
Q Well, there's several places. First is --
MR. SLATER: Is it really? I just want to understand the question. You're asking, is McElvenny a subsequent article about the Hidajat group?
MS. COHEN: Yes. Same cohort.
Q So page 849, assembly of study cohort, did you read that section?
A Yeah.
Q And then also --
A But the study it references to in previous analysis, Reference 6, is not Hidajat.
Q But look at page 854 also.
A It was also published before Hidajat.

Page 357

Q It's the same --
A McElvenny.
Q It's the same cohort.
A Okay. I haven't seen evidence of that yet. But I'll keep looking.
Q Let me show you this. This may clarify it.
Also, if you want to look at page 854, it talks about it being the same cohort. It talks about the prospective cohort based on the consensus in the industry carried out in 1967.
A Page 854, you said?
Q Yes.
A I'm still not finding any reference here that says it's the same cohort as Hidajat.
Q And we can deal with that later. But look down here.
It says on page 854, "Third -- on this study -- we had no information on smoking or any other important risk factors such as work in other industries, exposure to asbestos or

Page 358

diet. This omission could have resulted in a bias in those SMRs potentially affected by those risk factors. Our findings will be subject to multiple significance testing."

Do you see that part?

A I see that part. But I don't even know what this study deals with, who these patients are. That statement that you read, I agree that's what it says in this paper. I have no idea what means or what the context is. It means nothing to me at this point.

Q I understand. This wasn't part of your reliance list. This wasn't something you looked at. Let's just agree on that; okay?

A Okay. Are we moving past this?

Q Yes.

A I just want to be clear. That statement that we just read in this paper, as far as I understand it, has no relevance to my report.

Q You don't believe it has any

Page 359

connection to Hidajat?

A I've never seen it before. I don't know what it means, what it says or who the patients are. So at this point, I ascribe it no value.

Q Understood.

There's a lot of studies that you didn't look at; correct?

MR. SLATER: Objection. Is that argumentative?

MS. COHEN: No, not at all.

Q In general, you didn't intend in your 33-page report to cover every article that exists out there, did you?

A I read all the ones I found that seemed relevant and important.

Q But after the nine expert reports and defense side came in, did you make any effort to find out who they cited to, what articles they cited and try to review those?

MR. SLATER: Objection. You can answer.

A Other than one, I didn't see

Page 360

any of the other reports. And I didn't look up any of the literature.

Q Understood.

A Catenacci.

Q So your report on page 21, it says, "Amino acids in proteins are one of the building blocks of nitrosamines."

You see that on page 21?

A Let me just find that. Yes. I see that sentence.

Q And there's no cite there; correct?

A True.

Q How are nitrosamines produced through amino acids?

A So when you have a nitrosamine, or formally, N-nitrosamines, nitrogen group containing nitrosamines, are amines which an amino acid produces an amine. And a nitrosamine is attached to it. Nitrites would be a common donor of the nitrosamine group. So under specific conditions, particularly under acidic conditions, proteins or amino acids and nitrosamines and other

Page 361

nitrogen-containing compounds can form nitrosamine.

Q That happens inside the body; correct?

A Well, it can happen endogenously or exogenously. It can happen outside of any body. It can happen in a lake.

Q Would you agree that fruits and vegetables are a major source of ingested nitrates and nitrites?

MR. SLATER: Objection. You could answer.

A Different fruits and different vegetables have a different amount of nitrate and nitrite. Nitrate is not really harmful to the best of my recollection. Nitrites are. Also, there are certain foods that aggregate the effect of nitrites, Vitamin C-containing fruit foods, which would be a lot of fruits.

Q Speaking of fruits, would you agree that food that we all consume is typically composed or comprised of

Page 362

tens of thousands of different types of molecules in compounds?
A Tens of thousands?
MR. SLATER: Objection. You can answer.
A I don't have a specific opinion as to how many molecules are in an average -- how many different types of molecules are an average.
Q I want to ask you about -- because we talked a lot today. And I want to make sure we mark the binders before we go.
Your research approach when you said you found most of the articles, you did the searching, how did you go about searching for the articles in this case? What did you search?
A Nitrosamine -- well, okay. Let me just back up a little bit. I approached this the way I would try to describe the background of a scientific or medical question in a research article. And that would be to start with typically a search of PubMed, PubMed

Page 363

database of Peer Review articles. And to do that, I would search for key terms: Nitrosamine, NDMA, dietary NDMA, NDMA cancer, whatever else. I would also look to statements by regulatory bodies, international agencies, WHO article, which we haven't had a chance to talk about yet, unfortunately, WHO, IARC. And that's the way I would frame -- frame a discussion of a background question in a scientific paper.
Q So my question again was just to make sure I have down what search terms you used.
You said nitrosamine?
A NDMA, nitrosamine. I didn't keep a list of what search terms I used.
Q You didn't keep the search --
MR. SLATER: You're still answering?
THE WITNESS: Yes, I was.
MR. SLATER: Continue.
THE WITNESS: Okay.
A Right. I searched on

Page 364

multiple occasions. I would try to come up with different terms to try to capture as much of the literature as I could.
Q Did you share the search results with counsel?
A No.
Q I know that the question before you answered, that you were the one that found most of the articles, not counsel finding them for you; is that fair?
A Yes.
Q And again, you shared them with counsel?
A Yes.
Q The articles?
A Yes.
Q Your report on page 5, I don't think I asked you about this. But I want to make sure I cover it.
The top of page 5, you state, "Moreover, it's probable that individuals who are predisposed to cancer for any reason, genetic or environmental, have an even greater likelihood of

Page 365

developing cancer following and in part as a result of ingestion of NDMA or NDEA at the levels established with the contaminated Valsartan."
No cite there, is there?
A That's my professional opinion based on my review of the Peer Review medical literature, my knowledge of cancer biology.
Q And you can't offer a cite to support that, can you?
MR. SLATER: Objection. You can answer.
A It's my professional opinion, yes. I didn't pull that from a different document. I included that for myself, based on the Peer Review literature that I reviewed, I included in my report.
Q Can you give us any cite that stands for the proposition that individuals who are predisposed to cancer for any reason have a greater likelihood of developing cancer following ingestion of NDMA or NDEA?

Page 366

A Well, it's a scientific inference based on the fact that we know NDMA is an alkylating -- or when it's metabolized, NDMA is an alkylating agent which causes methylguanine formation. Methylguanine is one of the most mutagenic nucleic acids known to man.

So if you already have a problem predisposed to cancer, it's a perfectly reasonable scientific inference based on the mechanism of injury that those people would be at increased risk.

Q I understand that's your inference. I understand that's what you're saying.

Is there any article citation to give us that you believe supports that?

A As we spoke about before, there are different levels of evidence and different weight that you could put on different studies. But to get to the specific -- I want to be very responsive to your particular question. I would say that Pottegård does provide preliminary

Page 367

evidence in that regard.

As I said, the fact that Pottegård's trends -- and I admit they're not significant at this point. So I'm not saying it's definitely true. I'm saying that there's reason to believe it's true. The trends for increased cancer in Pottegård work for colon cancer and uterine cancer. Colon cancer and uterine cancer are the two most common cancers amongst patients with Lynch Syndrome.

So I think it is -- certainly when you have the mechanistic evidence, and we know the mechanisms by which NDMA does cause mutations, then we have at least preliminary data, showing that the cancers that were trending towards significance in Pottegård are those associated with Lynch which would be a genetic predisposition syndrome to cancer. I think that that supports my evidence-based hypothesis here.

Q Well, on the -- are you aware of any studies that demonstrate

Page 368

that individuals with Lynch Syndrome have an increased risk of cancer following exposure to NDMA and NDEA?

MR. SLATER: Objection. You can answer.

A There have not been any studies to date about patients with Lynch Syndrome exposed to NDMA and NDEA.

Q The part where we're reading where you don't have a cite on the top of page 5 because of your professional opinion?

A Yeah.

Q I heard you say that.

But it's your professional opinion; right?

A Yes.

Q And I think you said that's your supposition, did you say?

A Maybe.

Q What genetic factors are you talking about here that predispose an indication of cancer? What factors are you referring to?

A Well, there are a number

Page 369

of -- quite a few, actually, genetically factors that could predispose someone to cancer. The one that comes to my mind most acutely in this context is -- as we've discussed, Lynch Syndrome. But there are any number of other cancer predisposition syndromes.

Familial adenomatous polyposis, for example, causes hundreds of colon polyps. If you start ingesting something that cranks up the rate of mutation in those polyps, you could be in similar trouble. I mean we could talk about a lot of them and what would be plausible hypotheses for why they would put someone at an increased risk for cancer. But I think the early data points towards Lynch Syndrome as being relevant.

Q You also mentioned environmental factors.

Which ones are you referring to when you said that on line 2, page 5 of the supposition?

A Well, I mean it's part and

Page 370

parcel of the same -- same line of thinking that if you're exposed to something that is injuring your DNA and then you take another substance that injures your DNA, that's bad, to speak technically.

So smokers or given that gastric cancer has come up in quite a few of the dietary studies very commonly, helicobacter pylori infection is a very common cause of gastric cancer. So people who had that infection and were exposed to large amounts of nitrosamines might well be at increased risk. And the data that would support that, the dietary studies, showing gastric cancer is one of the main cancers associated with increased dietary NDMA would support that supposition as well.

THE WITNESS: Can I ask how much time we have left so we can determine whether to do a break now or plow through?

MR. SLATER: How much time are we in, Mr. Videographer, please?

Page 371

THE VIDEOGRAPHER: Six hours and 41 minutes.

MR. SLATER: It's not possible.

MS. COHEN: Which part's not possible?

MR. SLATER: He said six hours and 41 minutes. He said we were at 5 hours and 42 minutes before.

MR. SANJABI: That was an hour when we went back on.

MR. TRISCHLER: We could stop for a minute.

MR. SLATER: We don't need to stop for a minute.

THE WITNESS: No. If it's 18 minutes, I'm good.

MR. SLATER: Let's just keep going. You're still going; right?

MS. COHEN: Yes.

MR. SLATER: Let's keep going.

MS. COHEN: Do you need to go, though?

Page 372

MR. TRISCHLER: Go ahead.

Q Let me have you turn to page -- I'm really trying to get through and finish up the best I can. So page -- no regulatory agency that you've come across has classified NDMA or NDEA as a known human carcinogen. You agree with that; right?

MR. SLATER: Objection. You can answer.

A It's classified by most as a probable human carcinogen.

Q We went through all of it; no one classified it as a human carcinogen; true?

A My understanding is that it's a probable human carcinogen according to the regulatory agencies.

Q You would agree that no regulatory agency anywhere in the world has classified it as a known carcinogen; true?

MR. SLATER: Counsel, didn't he just answer that question twice in a row?

Page 373

MS. COHEN: He actually didn't.

MR. SLATER: You can answer it again, Doctor.

A To the best of my knowledge, it's classified as a probable human carcinogen.

Q And, therefore, not a known human carcinogen; true?

MR. SLATER: Objection.

A Yes, to the best of my knowledge.

Q Right.

Page 23, I want to ask you a question about that in your report.

The part here on the latency periods where it says, "The latency for cancer causes in whole or in part contaminated Valsartan -- I'm just going to ask you there.

This part about the bell curve being the likely latency curve, again, you have no cite there; that's because you don't have anything to cite there; right?

Page 374

MR. SLATER: Objection. You can answer.
A Well, again, that's an opinion based on my knowledge of cancer biology, cancer pathology. And it's a typical -- it would be typical for latency periods to be at least somewhat bell-shaped.
Q Based on your experience?
A Yes, and my knowledge of the medical literature.
Q But, again, you didn't cite to anything, nor can you cite to anything right now; true?
MR. SLATER: Objection. You can answer.
A I didn't cite to anything clearly here. But I mean, that's just the way cancers work. It's not like smokers get lung cancer precisely 20 years and 17 days after the first cigarette. There's some spectrum to it. Some get early cancer; some get late cancers. This is the way cancer physiology, pathobiology tends to work.

Page 375

Q Are there particular types of cancers that you believe that NDMA and NDEA more likely caused in animals?
A In animals?
Q Yes.
A Yeah. Give me a moment.
Q Okay.
A So in the IARC monograph on nitrosamines and NDMA, it says specifically -- and I reference this paragraph -- "N-nitrosodimethylamine is carcinogenic, and all animal species tested."
It lists a bunch of animals, including one I never heard of, called a Mastomy.
"It induces benign and malignant tumors following administration via various roots, including digestion and inhalation in various organs and various species. It produces tumors of the liver, kidney and respiratory tract."
So as far as the animal studies go, I have no specific feeling or knowledge -- I should say knowledge to

Page 376

countermand IARC's statement there.
Q What about in human beings? Are there particular types of cancers that you think are most likely when again caused by NDMA and NDEA in your opinion, even understanding that we're obviously in disagreement with?
A Yeah, certainly.
I think you have to start with the dietary studies, what cancers were we seeing in the dietary studies. And from the dietary studies, it seems the GI tract, specifically the stomach, the colon and in particular, the rectum, seem to be target-oriented.
I would also say that liver would be a high-risk organ based, A, on the animal studies; B on Gomm. And then the dietary studies also point to potency with respect to lung cancer. So those are the ones that preliminary data or in some cases fairly well-established data are pointing to as the most likely cancers. That's not to say that those are the only cancers that could be caused

Page 377

by NDMA ingestion. But you asked most likely. And I'm giving you the data on what is most likely.
Q Are most human beings exposed to the medical sources of ionizing and radiation?
MR. SLATER: Objection. You can answer.
A I don't know.
Q Are most human beings exposed to asbestos in the environment?
A Definitely.
Q When individuals are exposed to more than one kind of mutagen in their lifetime, can you determine as between them, which one causes cancer?
MR. SLATER: Objection. You can answer.
A It's a very broad question. In some instances, yes; in some instances, perhaps not.
Q Carcinogens from cigarette smoking enter the bloodstream?
MR. SLATER: Objection. You can answer.

Page 378

A Yes.
Q Does cigarette smoking cause cancer in human beings in every tissue?
MR. SLATER: Objection. You can answer.
A No. It goes back to the concept we talked about before of multi-specificity. It's not every tissue. But it's also not entirely restricted tissues either.
Q You said in your report --
A For example, cigarette smoking causes bladder cancer. So nobody is inhaling a cigarette through their urethra, hopefully. So the carcinogens are getting into the bloodstream.
Q On page 5, you had a comment about -- I can't find it here -- about -- let's see -- "Mutagenic effects likely greater in organs in which the cells replicate frequently (e.g. gastrointestinal tract)."
It's on the bottom. That's the -- on the bottom of 5.
A Okay. I'm looking. Yes.

Page 379

Q Which tissues in the human body have the highest proliferation rates?
A Well, as the example I give here, gastrointestinal tract, skin, blood cells, hematolymphoid cells.
Q And which ones --
MR. SLATER: I'm sorry. Did you finish?
MS. COHEN: I thought he said yes.
A I think so. Those are the vast ones.
Q Which ones would have the lowest proliferation rates?
A Neurons are the lowest. Liver cells are fairly long-lived as well in the absence of an insult. Any organ can be stimulated to proliferate. Any cell can be stimulated to proliferate. And there are many different insults to the organ that can cause that. But in the resting state, sort of the homeostatic state, the things I said are applicable.

Page 380

MS. COHEN: I think I'm going to pass the witness now. I don't know if we want to try to finish or not. But I'm going to cede the witness. I'll reserve additional questions if I need to. But I'm largely finished.
MR. TRISCHLER: Let's go off the record, please.
THE VIDEOGRAPHER: We are now off the record. The time is 6:08 p.m. Eastern Time.
(A short recess was taken.)
MS. COHEN: I'm marking 27, which is the initial production. It's an index of what you sent; 28 is a second production that you sent. And we typed it up; 29 is a third production that you sent; 30 is the fourth production that you sent; and then 31 is the Jakszyns article; and we have 32 which is the Doctor's 2002 WHR article binder.
(The above-referred-to document was marked as Exhibit 27 for

Page 381

identification, as of this date.)
(The above-referred-to document was marked as Exhibit 28 for identification, as of this date.)
(The above-referred-to document was marked as Exhibit 29 for identification, as of this date.)
(The above-referred-to document was marked as Exhibit 30 for identification, as of this date.)
EXAMINATION BY
MR. GALLAGHER:
THE VIDEOGRAPHER: We are back on the record. The time is 6:26 p.m. Eastern Time.
Q Good afternoon, Dr. Lagana. My name is Patrick Gallagher. I'm a partner with the law firm of Duane Morris. We represent the ZHP parties. I have just a few very limited questions for you.
A Okay.
Q Do you have your report in front of you? Can you turn to page 8?
A Yes.

Page 382

Q And the heading on the top of that page is "ZHP Nitrosamine Contamination Levels," the page you're looking at?
A Yes.
Q And on that page, you cite to some measurements of reported NDMA levels in certain batches of Valsartan, identify the lowest, the 3.4 ppm; highest, 188.1 ppm. Do you see that?
A I see it.
Q Those measurements are measurements of NDMA in Valsartan API. You understand that?
A Yes.
Q And you would agree with me that none of the individuals are patients who were prescribed Valsartan took Valsartan API? They all were ingesting finished dosage form; right?
A Yes.
Q And also, either in this section of your report or anywhere else in your report, you didn't consider or take into account the amount of time that

Page 383

a finished dosage form incorporating ZHP Valsartan API was being sold and distributed to patients, did you?
MR. SLATER: Objection.
A Could you rephrase that?
Q Sure.
You identified here, levels -- reported levels of NDMA in Valsartan API that was manufactured by ZHP; is that right?
A Yes.
Q And that Valsartan API was incorporated into finished dosage forms?
A Yes.
Q Dr. Lagana, in this section of your report or anywhere else in your report, you did not consider the amount of time that any finished dosage -- a finished dosage form incorporating Valsartan API manufactured by ZHP is actually available on the market and being distributed to patients?
A I don't believe I made reference to that set of data in my report. But I certainly saw some

Page 384

information getting at the root cause of the impurity and when it was thought that it likely started until the point where Novartis discovered it.
So in my thinking, yes, I took into account, you know, how many years such contaminated medicines were on the market. I don't recall if I made a specific reference to that in my report.
Q So you haven't -- in reaching your opinions in your report, you haven't relied on it?
MR. SLATER: Objection. You can answer.
A Well, in my reliance list are regulatory press releases and others that talk about the root cause and the year in which the processing, manufacturing process changed. And as I said, it did shape my thinking. So I provided those reliances. And I thought about those issues.
Q You thought about them, but in your report, you didn't identify that time frame in reaching your opinions?

Page 385

MR. SLATER: Objection. You could look at your report. But I object to the question. I'm not sure it makes sense. And I'm not even sure what you're getting at, counsel. A liability question?
MR. GALLAGHER: No.
A Yeah. I don't believe I made specific reference to the number of years by which ZHP was producing contaminated Valsartan.
MR. GALLAGHER: Thank you. I don't have any further questions.
EXAMINATION BY MR. SLATER:
Q Doctor, can you look at page 8, please, the top?
A Yes.
Q You see the first sentence? It says, "ZHP documented NDMA testing results in a chart of 783 batches manufactured with the zinc chloride process between December 28, 2011 and May 23, 2018."
Do you see that?

Page 386

A I see that.
Q And then you gave a summary of the levels between 3.4 parts per million and 188.1 parts per million; correct?
A Correct.
Q And I'm not going to go through all the other information.
Earlier, you were being asked by counsel about your opinions on latency and your reference to a bell curve in your report. Do you recall that?
A I do.
Q Let's talk about the front end of the bell curve.
Would that be the shorter term latency period for people who get cancer sooner after ingestion or exposure to the NDMA or NDEA?
A Yes.
Q At the front end of the curve, what would you say would be the shortest period of time in your opinion that somebody as a general proposition

Page 387

you would believe could get cancer due to the NDMA or NDEA as ingested in this matter?
A I think shorter -- less than a year would be hard to -- I would say probably a year or more.
Q On the back end of the curve, in your report, you referred to a period of 30 years or more.
What does that mean?
A Well, I mean, I think that this substance has damaged people's DNA. I think as time goes on, there's going to be more -- more cancer, more time, in my opinion, is going to lead to significantly more cancers. And it could take 30 years or more for those to be known.
Q You were asked by counsel about the increased risk, and you referred to the dietary studies, and it's my term, analogizing or being closely akin to the lower levels seen in the Valsartan pills. Do you recall testimony to that effect?

Page 388

A I do.
Q For the higher consumers who took higher levels as compared to the lower consumers who took lower levels of these contaminants, what would their increased risk be in comparison to the people who took the lower levels?
MS. COHEN: Objection. Foundation.
Q You can answer.
A I would expect the rates to be higher and potentially much higher, much higher risk depending on how much NDMA they inadvertently consumed.
Q I'm not going to go through your report.
But in your report, you addressed those cancers that were reflected in the literature with regard to both animals and humans.
Do you stand by what you put in your report based on your review of the Peer Review literature on the cancers that are shown in the published literature being related to the

Page 389

substances?
MS. COHEN: Objection. Form.
A I stand by everything in the report with respect to that.
Q Do you have the Gomm study handy which was Exhibit --
A I got it.
Q Please look at Gomm, page 360, 360.
A Okay.
Q In the right-hand column, just above the heading that says "Regulatory and Public Health Implications," there's a paragraph that says, "However, molecular mechanisms known for NDMA in the pathogenesis of liver cancer in experimental animals support an association with NDMA exposure in humans. It may be that NDMA exposure promotes cancer development in already existing, as yet undiagnosed early stages and thus hastens clinical manifestation."
I wanted to read that and ask you, counsel was earlier asking you

Page 390

about your opinion about the interaction of the NDMA or NDEA with somebody who has a predisposition of some sort, and, again, those are my words. And you were asked, was there any published Peer Review literature on that topic?

Is this published Peer Review literature addressing that topic at least in part?

MS. COHEN: Objection.

A It is.

Q Counsel asked you earlier about the Sörgel article which is Reference No. 2 to your report. Do you recall that?

A I do.

Q And you were asked about your analogy in your report to a pack of cigarettes. Do you recall that?

A I do.

Q And you went through the data and indicated that based on the amounts of NDMA noted, that would be comparable to a pack of cigarettes. You remember you said that?

Page 391

A I do.

Q I want to show you what we're going to mark as -- I guess we'll just mark it as Plaintiffs' Exhibit 1.

(The above-referred-to document was marked as Plaintiffs' Exhibit 1 for identification, as of this date.)

Q And I'm going to put a Post-it note on it in the interest of moving quickly here on a Friday afternoon. So I'm going to put P1 on it, on a Post-it note. I'm going to hand you one. I'm going to hand one to counsel. It's P1.

Is this an article that you're familiar with?

A It is.

Q When you compare that article to the Sörgel, Abdel-Tawab, et cetera, article, are there similar -- any similar authors?

A Yes. Abdel-Tawab I believe is a similar author. Let me just pull out Sörgel.

Page 392

Q And if you could look at -- and what I just handed you, which is page 5 out of 8 --

A Okay.

MR. SLATER: And I could tell you, this is a translation --correct, Chris? -- of a German article?

MR. GEDDIS: Yes.

Q If you look at page 5 out of 8 --

A Okay.

Q -- and if you look at the second paragraph, it says, "Accordingly, the mean intake of nitrosamines from food is estimated at a total of 0.3 ug per day. Smoking 20 cigarettes a day can generally increase the exposure to nitrosamines to 17 to 85 ug per day."

Is that of significance with regard to counsel's questions as to where you came up with the smoking a pack of cigarettes today and citing to Abdel-Tawab?

MS. COHEN: Objection to form.

Page 393

A Yes. I meant to include this as an additional cite at that point of the report. So 22 micrograms is 22,000 nanograms which is within the range of what's said here in 20 cigarettes.

And if you read the next sentence, it makes the inference in comparison with the 22 micrograms of NDMA alone can be obtained by taking a contaminated tablet from the present examination samples.

Q With regard to counsel's questions about the accuracy of your references, are you telling us that you saw this article, you were relying on it, but it was not specifically cited in the report?

MS. COHEN: Objection to form.

A Yes. It was inadvertently omitted.

Q Finally, you were asked about the FDA's statements previously;

Page 394

okay? You remember that? You were asked questions about a bunch of FDA statements.
A I do.
Q And one of them, which we marked as -- you don't have to find it, was marked as Exhibit 17, information about nitrosamine impurities in medications.
On page 4 out of 8, counsel read to you from the fourth bullet point that says, "Nitrosamine impurities may increase the risk of cancer if people are exposed to them above acceptable levels and over long periods of time. But a person taking a drug that contains nitrosamines at or below the acceptable daily intake limits every day for 70 years is not expected to have an increased risk of cancer."
In this case, based on the information that you've been provided, was the level of nitrosamines, specifically NDMA and NDEA, above or below the limits that were set by the

Page 395

FDA?
MS. COHEN: Objection to form and foundation.
Q You can answer the question.
A By and large above and in some instances, wildly above.
Q And lastly, counsel asked you a bunch of questions about the fact that people were allowed to keep taking their Valsartan until they spoke to their doctor.
Is that because the FDA did a balancing and a risk-benefit and said, well, if people go off their blood pressure medication in the short-term like in the next few days or weeks, they could die of things like strokes and heart attacks, whereas we're talking about a longer-term risk with these pills, so let's not have a bunch of people dropping dead from heart attacks and strokes while they get on to other medications? Was that your understanding of the FDA's thinking?
MS. COHEN: Objection to

Page 396

form, foundation, calls for speculation on his part.
A I do think that is probably what informed the FDA's thinking.
MR. SLATER: Thank you. I have no other questions.
FURTHER EXAMINATION BY MS. COHEN:
Q The only follow-up I have is on the new article that just suddenly appeared just now, which is Plaintiffs' Exhibit 1, this Abdel-Tawab article.
MR. SLATER: Just for one, counsel, I'm informed by Mr. Geddis you actually were provided that article. It wasn't referenced specifically in the report. But it was produced to you.
MR. GEDDIS: It was in the first production.
MR. SLATER: I just wanted you to know that.
MS. COHEN: I appreciate that.
Q So basically, this was not

Page 397

cited in your report; is that right?
A Correct.
Q And this was not referenced on the reference sheet in your report; correct?
A Correct.
Q The number of articles.
So you didn't have this at the time you issued your report on July 6th; correct?
A I definitely had this. I read this before I wrote my report. I meant I should have included this as a cite in my report. I overlooked doing that.
Q And I think you highlighted for us today, 34 different kind of errors and citation; is that a fair statement?
MR. SLATER: Objection. You can answer.
A Certainly on the three side of things, yeah.
Q How many other cites did you miss?
A I don't think any.

Page 398

Q This was just given to us in the last couple of days by Mr. Geddis.
Do you have this in your materials?
A I read this a while ago. I don't remember exactly when I gave Mr. Geddis the study, or the paper, I should say.
Q But regardless in terms of the quote in your report about the cigarettes, that citation was not in your report; correct?
A That citation should have been two citations. Both -- the Sörgel was appropriate. But also, I should have included a citation to Abdel-Tawab, who really makes the more direct reference to a pack of cigarettes.
Q Let me just quickly, just so I'm clear on that, if you don't mind, show me in this article where the -- in the Abdel-Tawab where the quote is written.
A Sure. Page 5, the second paragraph.

Page 399

"Accordingly, the mean intake of nitrosamines from food is estimated to be 0.3 micrograms per day. Smoking 20 cigarettes, a standard pack a day can generally increase the exposure to nitrosamines is 17 to 85 micrograms per day. In comparison with this, up to 22 micrograms of NDMA alone can be obtained by taking a contaminated tablet from the present examination samples."
So 22 is in between 17 to 85; thus, it is equal to the amount of exposure in a package of cigarettes.
Q So you're saying you read this article, you interpreted it as you interpreted it, and you included this statement in your report and didn't have any cite to it?
A Yes. I overlooked including this cite.
Q And sitting here today, you don't know how many other cites you've overlooked, do you?
MR. SLATER: Objection.
A I don't believe I overlooked any other cites.

Page 400

Q Well, if I had questioned you about this, would you have realized you overlooked this site?
MR. SLATER: Objection. You can answer.
A Probably not because if I had realized it before, I would have corrected it.
Q It was only because I focused on that sentence, not being supported by Reference 2, that you even noticed it; correct?
MR. SLATER: Objection. You can answer.
A Well, I was surprised I didn't find exactly what I was looking for in the article. And I knew there was something I had read about a German lab study. And this is something that we did produce and that I had reviewed. And this is definitely what I wanted to cite.
Q In the world of publishing, again, I guess usually the journals have people who are usually checking your work?
A The Peer Reviewers check, yeah. You can also issue a corrigendum for small little things like that.
MS. COHEN: Just quickly, we marked 27, 28, 29, 30, a list of the articles that were produced.
Can you show us, Chris?
MR. SLATER: He didn't say it was on the list.
MR. GEDDIS: They made their own lists. I'll go on Dropbox and pull it, so that we're pulling it from the same.
MS. COHEN: Can you just maybe tell us, let us know where we can find it?
MR. GEDDIS: I can do it in like two seconds.
MS. COHEN: So it was produced.
MR. SLATER: That's all I have. Thank you.
THE VIDEOGRAPHER: We are now off the record. The time is

6:48 Eastern Time. This concludes the testimony of Dr. Stephen Lagana.
(Time noted: 6:48 p.m.)

_____
DR. STEPHEN LAGANA

Subscribed and sworn to
before me on this _____day
of _____, 2021.

_____
NOTARY PUBLIC

I N D E X

E X A M I N A T I O N

E X H I B I T S

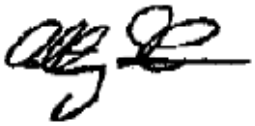
INDEX (Cont.)

INDEX (Cont.)

CERTIFICATION

I, ANTHONY GIARRO, a Shorthand Reporter and a Notary Public, do hereby certify that the foregoing witness, DR. STEPHEN LAGANA, was duly sworn on the date indicated, and that the foregoing, to the best of my ability, is a true and accurate transcription of my stenographic notes.

I further certify that I am not employed by nor related to any party to this action.



ANTHONY GIARRO

ERRATA SHEET

VERITEXT/NEW YORK REPORTING, LLC

1-800-727-6396

330 Old Country Road 1250 Broadway
Mineola, NY 11501 New York, New York
10001

NAME OF CASE: In Re: Valsartan, Losartan and Irbesartan Products Liability Litigation

DATE OF DEPOSITION: August 13, 2021

NAME OF DEPONENT: Dr. Stephen Lagana

PAGE	LINE (S)	CHANGE	REASON

_____
DR. STEPHEN LAGANA

SUBSCRIBED AND SWORN TO BEFORE ME
THIS ____ DAY OF _____, 20__.

_____ _____
(NOTARY PUBLIC) MY COMMISSION EXPIRES:

b

Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY. THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

Veritext Legal Solutions is committed to maintaining the confidentiality of client and witness information, in accordance with the regulations promulgated under the Health Insurance Portability and Accountability Act (HIPAA), as amended with respect to protected health information and the Gramm-Leach-Bliley Act, as amended, with respect to Personally Identifiable Information (PII). Physical transcripts and exhibits are managed under strict facility and personnel access controls. Electronic files of documents are stored in encrypted form and are transmitted in an encrypted fashion to authenticated parties who are permitted to access the material. Our data is hosted in a Tier 4 SSAE 16 certified facility.

Veritext Legal Solutions complies with all federal and State regulations with respect to the provision of court reporting services, and maintains its neutrality and independence regardless of relationship or the financial outcome of any litigation. Veritext requires adherence to the foregoing professional and ethical standards from all of its subcontractors in their independent contractor agreements.

Inquiries about Veritext Legal Solutions' confidentiality and security policies and practices should be directed to Veritext's Client Services Associates indicated on the cover of this document or at www.veritext.com.